EDISON

Hutchison China MediTech

Corporate update

Future stars are aligning

Pharma & biotech

Despite a strong run over the last 12 months, our increased valuation of $2.7bn suggests the market overlooks HCM's full R&D potential. Multiple catalysts are on the horizon in 2017/18; notably the China FDA filing for fruquintinib in CRC (full Phase III CRC data [China] at ASCO) and overall survival data from the savolitinib Phase II trial in c-Met-driven PRCC (could support a US NDA submission). Further progress of the early to mid-stage pipeline over time should retain investors focus. Ultimately, HCM's move to commercialise its innovative pipeline in its domestic market (and longer term in international territories) could provide a major source of uplift.

Year end	Revenue ($m)	Net profit* ($m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	178.2	8.0	14.6	0.0	254	N/A
12/16	216.1	11.7	19.6	0.0	189	N/A
12/17e	234.2	(21.1)	(34.9)	0.0	N/A	N/A
12/18e	262.5	(9.7)	(16.0)	0.0	N/A	N/A

Note: *Net profit and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

2017/18: Future stars are aligning

HCM and Lilly will submit the fruquintinib CRC China NDA in mid-2017; full data from the FRESCO trial will be presented at ASCO on 5 June 2017. Depending on the strength of the NDA submission packages and speed of China FDA, fruquintinib could launch in China in 2018. Phase II overall survival data on savolitinib in c-Met-driven PRCC later this year could support a US NDA application under breakthrough therapy designation, with potential to be HCM's first internationally launched asset (we expect launch in the US in 2018 by partner AstraZeneca, we assume under breakthrough therapy designation).

R&D day highlighted the three waves of innovation

The 29-30 March R&D days highlighted the scientific and commercial rationale of the broad oncology and immunology pipeline that underpins the R&D effort at HCM. Investors gained further insight into drug development at HCM plus a steer on the potential for multiple stock catalysts in 2017/18, including clinical trial results, regulatory filings and long-term commercialisation strategies in China.

China commercial platform to leverage new assets

In the medium term, we expect HCM to capitalise on its substantial China-based commercial presence by launching its unpartnered innovation platform assets into the domestic market through the commercial platform (CP) division; this would serve as a major source of uplift in economic returns.

Valuation: $2.7bn (£36.1/share, $22.6/ADS)

We have increased our SOTP valuation to $2.7bn (£36.1/share) from $2.4bn (£32.2/share), in the main due to progress in the R&D pipeline and upgrades to our CP forecasts after a stronger than anticipated FY16. The Innovation Platform is valued at $1,948.6m from $1,789m and placing CP's 2017e share of net profit on a 23.6x rating gives $788.8m (1,040p/share). Adding December 2016 net cash and netting out unallocated costs results in a value of $2.7bn. Approval(s), clinical data and/or deals should increase our risk-adjusted valuation.

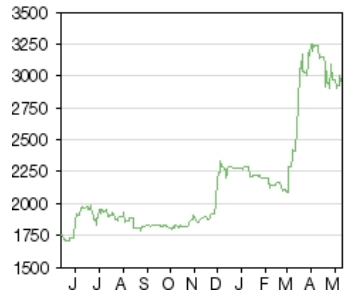
11 May 2017

Price	**2,962.50p**
Market cap	**£1,799m**
	US$1.25/£
Net cash ($m) at 31 December 2016	56.9
Shares in issue*	60.7m

*£ share price based on 60.7m ordinary shares; US$ price based on 121.4m American depositary shares, 1 ADS = 0.5 ordinary shares.

Free float	39.6%
Code	HCM
Primary exchange	AIM
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(7.4)	38.4	69.3
Rel (local)	(8.3)	34.9	41.2
52-week high/low	3252.5p		1710.0p

Business description

Hutchison China MediTech (Chi-Med; HCM) is an innovative China-based biopharmaceutical company targeting the global market for novel, highly selective oral oncology, and immunology drugs. Its established China Healthcare business is growing ahead of the market.

Next events

Fruquintinib FRESCO full data in CRC	5 June 2017
Fruquintinib China NDA CRC	Mid-2017
Savolitinib PRCC OS data	H217

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Edison profile page

Investment summary

This note discusses the key clinical and regulatory catalysts for the year ahead. In addition, we consider the insights gleaned from the company's R&D day(s) held in late March 2017, the increasing importance of the growing early- to mid-stage pipeline and how growth in its existing China-based infrastructure is set to capitalise on its unpartnered assets in the longer term. 2017/18 marks a transformational year for HCM as two of its internally developed tyrosine kinase inhibitors, fruquintinib (third-line CRC) and savolitinib (c-Met-driven PRCC) could be submitted to the China FDA (mid-2017) and US FDA under breakthrough therapy designation (late 2017/early 2018) respectively; the latter is dependent on the strength of the overall survival (OS) data expected from the Phase II PRCC trial later this year (and the global PRCC epidemiology study on 300+ samples). The launch of fruquintinib by partner Lilly in China (CRC) and/or launch of savolitinib in international markets by partner AstraZeneca (PRCC) would materially underpin 16 years of innovation in the making. For broader and more in-depth reports on HCM see our outlook notes Stellar Evolution and WCLC: Positive data highlights NSCLC pipeline .

Valuation: Still room to grow despite outperformance

We have increased our SOTP valuation to $2.7bn (£36.1/share) from $2.4bn (£32.2/share), in the main due to progress in the R&D pipeline and upgrades to our CP forecasts after a stronger than anticipated FY16. We use earnings-based multiples for HCM's Commercial Platform (subs and JVs), and a risk-adjusted NPV model for Innovation Platform, the MediPharma unit. We use a 23.6x multiple (in line with the sector average for Chinese peers) on our forecast 2017 net attributable profit (equity in earnings of equity investees, net of tax) for the SHPL, HBYS, HSP and HHO JVs of $33.4m, which results in a valuation of $788.8m. We use a risk-adjusted net present value method to discount future cash flows for the Innovation Platform division, which yields a valuation of $1,948.6m. Adding December 2016 net cash and netting out unallocated costs results in a value of $2.7bn.

Sensitivities: CK Hutchison reduces Chinese risks

HCM is subject to the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes, partnering setbacks, and financing and commercial risks. Expectations for the pipeline have increased and while our risk-adjusted NPV highlights the future sources of upside to the shares, the failure of one or more products to succeed would have a negative impact on the shares; savolitinib, fruquintinib and sulfatinib contribute ~65% to our valuation of HCM. CK Hutchison's involvement in HCM materially reduces the myriad of risks associated with any direct investment in China; however, it does mean investors are minority shareholders. Additionally, the limited available free float reduces the shares' liquidity.

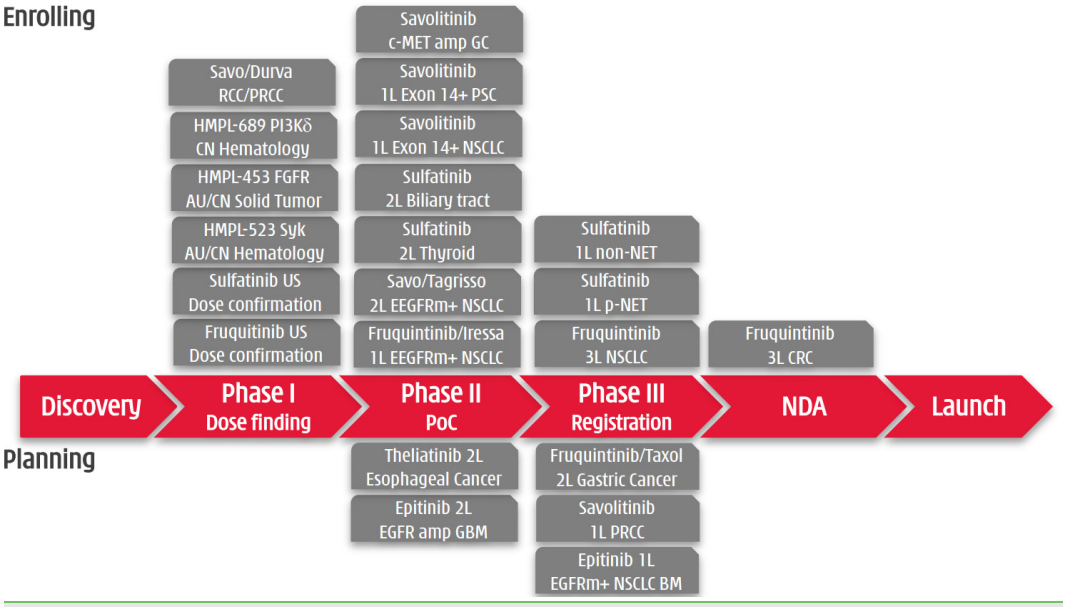
Financials: Healthy cash position

At the group level, 2016 revenues were reported at $216.1m (+21%), with net profits attributable of $11.7m versus a gain in 2015 of $8.0m. Revenues reported at the group level do not include the reported revenues of the Shanghai Hutchison Pharmaceuticals (SHPL) and Hutchison Baiyunshan Chinese Medicine Co (HBYS), 50/50 joint ventures that are accounted for using the equity method, with only the net profit contribution recorded. At 31 December 2016, the company held $103.7m of cash and cash equivalents and short-term investments at the group level, with $91.0m in further cash and equivalents held at the 50/50 JV level, which is not consolidated at the group level; all told, with HCM's additional access to a total of $70.0m of bank facilities, we do not envisage any funding gap in our near-term forecast period despite the additional R&D investment requirements.

2017/18: Future stars are aligning

HCM is approaching an inflection point; it is on the brink of transforming its Innovation Platform (IP) business into a late-stage portfolio story with potential first drug launches from 2018 in China and international markets. The clear strategic vision presented by HCM management is the focus on target selectivity, with the aim of having a potential first-in-class or best-in-class portfolio of targeted cancer drugs. HCM's aim is to be one of the first globally focused biopharmaceutical companies to emerge from China. On that subject, the R&D day (held 29 March in London and 30 March in New York City) served to highlight the scientific talent at HCM, a team of 330 China-based scientists and staff led by CSO Weiguo Su (Harvard graduate PhD, ex-Pfizer), who has created HCM's Innovation Platform (IP) R&D engine (focusing on targeted treatments based on molecular chemistry) and has led all pipeline discovery during his 12-year tenure at HCM. As a result, the company has eight internally developed, next-generation tyrosine kinase inhibitors (TKIs) spanning 30 active clinical trials (mainly oncology indications). All drug candidates were designed in house and utilise co-crystal structures to optimise binding to on-target proteins (for potency) and minimise binding to off-target proteins (for selectivity). Exhibit 1 highlights the key programmes at HCM across the various drug development stages.

Exhibit 1: Key pipeline programmes



Source: Company presentations

Three waves of innovation

HCM boasts a deep TKI portfolio for oncology that spans from discovery to late stage pre-registration assets. In the longer term, we anticipate combination trials to feature heavily in the clinical trial programmes as HCM combines a number of its own products to address the resistant cancer populations. While development of therapies targeting tumour angiogenesis, tumour driver gene alterations and tumour immune evasion has made significant advances in improving overall survival in cancer patients, efficacy can be limited and resistance often develops with single drug therapy that target a single axis of tumorigenesis. HCM's focus on target selectivity and thus potential for lower toxicity should lend the portfolio to rational combination therapies based on tumour-specific features.

First wave of the pipeline stepping closer to commercialisation

The first wave of the innovation pipeline (lead candidates) consists of fruquintinib, savolitinib, sulfatinib and epitinib for various cancer indications and has the potential to transform HCM into a fully integrated, international biopharmaceutical company. 2017 is set to be a defining year, with HCM and partner Lilly set to submit the China NDA in mid-2017 for fruquintinib (based on the positive, top-line pivotal Phase III FRESCO trial results in third-line colorectal cancer. Investors will be looking to ASCO 2017 (5 June) when the full data results from FRESCO will be presented. This marks the first full data from a pivotal Phase III trial to be published from HCM's pipeline, underpinning the scientific rationale behind its R&D strategy. An accelerated review process in China could translate to a 2018 launch time frame if approved. Furthermore, if the OS data on savolitinib in PRCC are compelling, HCM and partner AstraZeneca (AZN) could submit a US NDA submission under breakthrough therapy designation in late 2017/early 2018, which could result in a US launch in 2018 for this indication.

Other late-stage, pipeline-related newsflow expected over the course of 2017/8 includes data from both the NSCLC Phase IIb Tagrisso and Iressa combinations (for savolitinib), Phase III third-line NSCLC (fruquintinib) and ongoing Phase II in thyroid cancer at ASCO on 5 June (sulfatinib), mature PFS data from the epitinib Phase Ib/II proof-of-concept trial, which is ongoing in China.

Second wave of the pipeline moving towards proof-of-concept trials

Longevity for R&D-driven biopharmaceutical companies is dependent on having a pipeline of innovative assets that span from the early development phase. HCM's second wave of innovation candidates (theliatinib, HMPL-523, HMPL-689, and HMPL-453) are in dose-escalation Phase I and/or are poised to enter Phase Ib/II clinical development (POC clinical trials) for oncology and immunology indications. HCM hopes to generate enough data in the next 12-18 months to sufficiently demonstrate proof of concept for these compounds. These assets contribute little or zero to our valuation (we typically include Phase II assets for HCM in our valuation) and as such we would anticipate progress to POC to increase our risk-adjusted valuation of the company. Furthermore, in the medium term, we expect HCM to capitalise on its substantial China-based commercial presence by launching some of these unpartnered assets into the domestic market through its CP division; this would serve as a major source of uplift in economic returns. International launches are an additional possibility in the long term.

Third wave: The early research strategy

The early-stage research strategy at HCM includes drug classes that are designed to target cancer immunity and HCM is hoping the third wave of assets can be combined with its existing drug portfolio. Four or five programmes against novel immuno-oncology targets could enter into clinical-phase development over the next three to four years, at which point HCM should have a portfolio of approved drugs that would form the basis of combination trials. The early-stage research engine at HCM and strategy for combination therapies demonstrates a long-term commitment to innovation. Exhibit 2 highlights the main catalysts for the year ahead.

Exhibit 2: Key late stage portfolio news flow in 2017/18

Product	Indication	Next news	Timing
Savolitinib	PRCC	Phase II OS data	H217
		Global Phase III initiation (monotherapy)	Q217
		Potential US NDA submission	Late 2017/early 2018
	NSCLC	Phase IIb data in second-line NSCLC with Tagrisso and Iressa	H217
		Global Savolitinib/Tagrisso combo registration trial decision	H217
Fruquintinib	CRC	China NDA submission (third-line CRC)	Mid-2017
		China Phase III full data (FRESCO) at ASCO	June 2017
	NSCLC	China Phase III (FALUCA) data top line read out	2018
Sulfatinib	NET	Phase II POC data in thyroid cancer (early data at ASCO)	June 2017
		Initiate US Phase II study in NET	H217
Epitinib	NSCLC	Initiate China Phase III; start US development	H217/2018

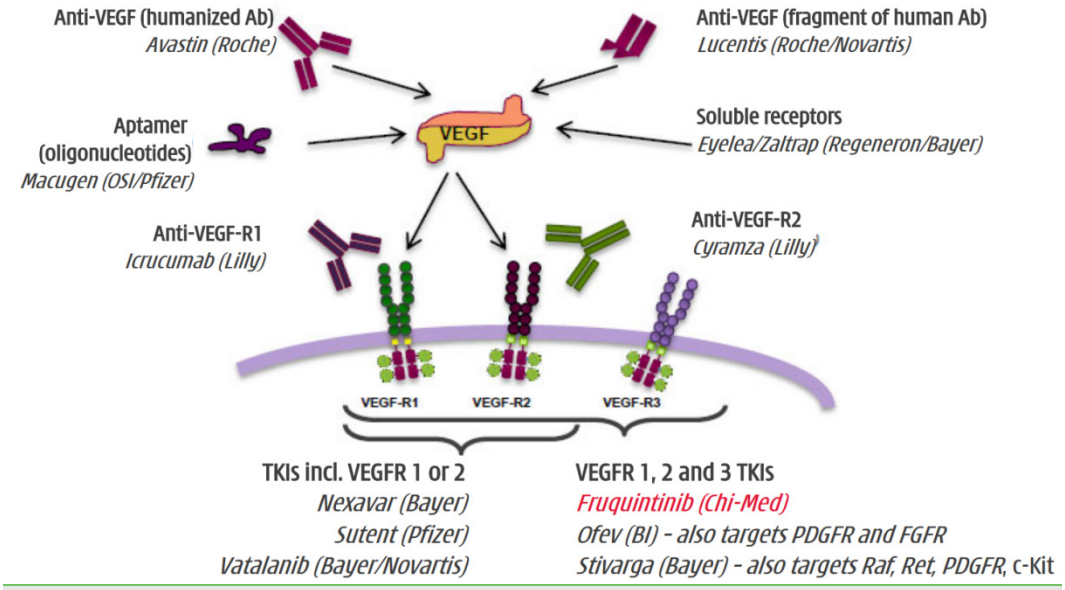
Source: Company presentations, Edison Investment Research

Fruquintinib differentiated VEGFR inhibition

Fruquintinib's most advanced indications are in CRC (third-line) and NSCLC (third-line) in China, and data from the pivotal FRESCO Phase III in CRC will be presented at ASCO on 5 June. The drug is an oral small molecule that is a highly selective VEGFR1, VEGFR2 and VEGFR3 inhibitor (preclinical trials demonstrated fewer off-target toxicities, enabling higher drug exposure leading to 24 hours/day VEGFR receptor inhibition). First-generation VEGFR inhibitors such as Roche's Avastin (monoclonal antibody administered intravenously) revolutionised the treatment of cancer by targeting the growth of blood vasculature that is essential for tumour growth (anti-angiogenesis). Oral, small molecule VEGFR inhibitors Nexavar (Bayer) and Sutent (Pfizer) are approved for use in some cancers (Nexavar in HCC and RCC, Sutent in GIST, RCC, and PNET). This highlights the unmet need for an oral anti-angiogenesis agent with a demonstrable impact on progression-free survival (PFS) in cancers such as NSCLC, CRC and breast cancer.

What differentiates fruquintinib from Nexavar and Sutent is its potent anti-VEGFR3 inhibition; the others inhibit VEGFR1 and VEFR2 only (Exhibit 3). Potent VEGFR3 activity could have utility in breast and lung cancer. Avastin is not approved for use in breast cancer; FDA removed the breast cancer indication from its label in 2011 due to lack of efficacy in this indication (it failed to improve survival for patients with mBC). Furthermore, Lilly's VEGFR inhibitor, Cyramza, failed to demonstrate efficacy in breast cancer. The scientific community hypothesises that both drugs have failed in this indication due to lack of lymph angiogenesis control. It is believed that drugs, such as fruquintinib that inhibit VEGFR3 activity could, by interfering with lymph angiogenesis, have utility in breast and lung cancer. Fruquintinib's ability to cover VEGFR1, 2 and 3 equally well with low off-target toxicity and its low risk of drug to drug interactions make it a suitable candidate for combination studies, and it serves as a differentiation factor from existing anti-angiogenesis agents.

Exhibit 3: VEGFR inhibitors



Source: Company presentations

FRESCO CRC full data at ASCO 2017; China FDA submission mid-year

Following positive, top-line pivotal Phase III trial results for fruquintinib in third-line colorectal cancer, HCM and partner Lilly are preparing for a China NDA submission in mid-2017; this represents the first China-based oncology innovation to succeed at Phase III. The China-based FRESCO study evaluating 416 patients who had failed at least two prior chemotherapies in CRC demonstrated a clinically meaningful and statistically significant increase in both overall survival and progression-free survival compared to placebo. Furthermore, the trial did not identify any new or unexpected safety issues. The positive top-line Phase III dataset highlights the selectivity hypothesis of HCM's TKI pipeline. The full data will be presented at ASCO on 5 June 2017. Depending on the strength of the NDA submission packages and speed of the China FDA, we anticipate fruquintinib launch in China in 2018. The speed of any approval in China is less clear than with the US FDA, but we expect it to take between six and 12 months. We assume the speed will depend on the quality of the data and a faster approval (nearer to six months) could be achieved if the Phase III data are compelling. In the US, a Phase I bridging study in Caucasian patients will initiate in 2017. This study should determine the dose required to take fruquintinib into US Phase II/II studies across its differing indications in preparation for a US NDA submission. Contingent on strong proof-of concept (POC) and Phase III results in fruquintinib clinical trials in China, Eli Lilly may exercise its option to co-develop fruquintinib globally under the terms of the 2013 licence agreement. We expect fruquintinib to enter US Phase II/III trials regardless of whether Lilly exercises its option.

FALUCA pivotal NSCLC programme top-line data expected in 2018

FALUCA, the Phase III registration trial in China, was initiated in December 2015 for third-line treatment in NSCLC, following a positive Phase II POC trial that reached the primary endpoint of PFS with no unexpected safety issues. FALUCA is a double-blind, placebo-controlled Phase III evaluating fruquintinib 5mg once-a-day plus best supportive care in four-week treatment cycles (three weeks on drug, one week off). 521 patients are being randomised to the fruquintinib group or the placebo group at a ratio of 2:1 across 45 centres in China. The primary endpoint is overall survival; secondary endpoints include progression-free survival, objective response rate, disease control rate and duration of response; top-line data are expected in mid-2018; trial enrolment is estimated to complete in Q317 and database close is anticipated by mid-2018. Further trials evaluating fruquintinib in NSCLC are planned for 2017/18, likely in combination with other targeted

therapies, eg using two oral TKIs to target EGFR and VEGFR simultaneously. Notably, at the R&D day the company indicated that the Phase II safety run in combination with Iressa in first-line, advanced NSCLC patients is in progress and expected to complete by year end 2017; the Phase II/III trial will follow once the safe dose has been established.

Global development to focus on combination studies

At the American Association for Cancer Research (AACR) 2017 meeting, HCM presented data on fruquintinib in combinations with targeted therapies or immune checkpoint inhibitor in preclinical tumour models. While at a very early stage, HCM reported that the efficacy observed in these models suggested that simultaneous blockade of tumour angiogenesis and tumour cell signalling or immune evasion might be a promising approach in improving treatment outcomes. Fruquintinib's low risk of drug-to-drug interactions due to lack of Cytochrome P450 (CYP450 family of isozymes responsible for the metabolism of several drugs within the body) inhibition/inducing is favourable for potential in combination treatment regimens, given that many drugs are metabolised through the cytochrome P450 enzyme pathway. To compete in the global anti-angiogenesis inhibition setting, clinical trials will focus on more proprietary combination studies (eg fruquintinib plus savolitinib in clear cell renal cell carcinoma, fruquintinib plus Iressa in first-line NSCLC, fruquintinib plus Taxol in second-line gastric cancer). The Phase II/III trial in second-line gastric cancer is evaluating the combination of fruquintinib to paclitaxel (Taxol) compared to paclitaxel alone. Approximately 540 patients are being randomised between the two groups and an interim analysis will take place after the first 100 patients are treated. HCM expects full enrolment by H219; we anticipate top-line data could be available early 2020.

Peak sales and China commercialisation opportunity

We forecast global peak sales for fruquintinib of $2.3bn across the potential CRC, NSCLC and gastric cancer indications. Exhibit 4 details our assumptions. We have delayed our international launch year assumptions for CRC, NSCLC and gastric to reflect the ongoing US bridging studies and the uncertainty of time frames of US Phase II/III trials related to Lilly's international co-development optionality. Timelines to reach our peak sales assumptions have additionally been pushed back; all else being equal, we have increased our peak sales numbers slightly as a function of our expected 2% pa price increase from launch year.

Exhibit 4: Fruquintinib peak sales forecasts

Product	Indication	Launch year/ peak sales China	Launch year/ peak sales ROW	Assumptions
Fruquintinib	CRC	2018/2024 $106.6m	2021/2026 $654.4m	Global new cases (1,477,000), China new cases (283,000). China penetration 1%, $2,500 per month, 12-month treatment duration. ROW penetration 0.8%, $5,000 per month, 12-month treatment duration.
	NSCLC	2020/2025 $297.6m	2021/2025 $721m	Global new cases (1,690,000), China new cases (623,000), China penetration 1.5%, $2,500 per month, 12-month treatment duration. ROW penetration 1.0%, $5,000 per month, 12-month treatment duration. We assume mainly in third-line NSCLC, but some use in additional lines.
	Gastric cancer	2019/2026 $141.7m	2021/2026 $391.9m	Global new cases (1,034,000), China new cases (454,000). China penetration 1%, $2,500 per month, 12-month treatment duration. ROW penetration 1%, $5,000 per month, 12-month treatment duration.
	Deal economics			Deal economics: $86.5m in upfront and milestones from Lilly royalty rate 15-20% on China, 11% ROW. Majority of development costs, all commercial costs in China.

Source: Edison Investment Research. Note: FX rate US$1.25/£.

Savolitinib

Savolitinib in c-Met-driven PRCC has potential to be HCM's first internationally launched asset (with possible regulatory filings in 2018 [in the US] by partner AZN). Savolitinib is a novel, orally administered, small molecule TKI. The drug is a highly selective inhibitor of the c-Met signalling

pathway and targets patients with resistant cancers whose tumour type tests positive for MET amplification or overexpression. Savolitinib is 1,000 times more selective for c-Met than the next kinase (PAK3).

MET gene amplification, c-Met overexpression, mutations and cross-talk with other receptors are all drivers of c-Met aberrations. These aberrations are present in a range of different cancers and are often drivers of resistance, eg MET activation is associated with poor prognosis in NSCLC and is also associated with EGFR TKI resistance. Savolitinib is hypothesised to have a greater beneficial impact on c-Met-driven tumours than approved multi-kinase inhibitors; the drug could straddle multiple lines of treatment as monotherapy and in combination with other novel cancer agents in the first-, second- and third-line solid tumour settings, particularly in EGFR-resistant patient subgroups. Multiple trials are currently underway; key to these is a global Phase III in c-Met positive PRCC, which will kick off shortly. Top-line data are expected in 2019. The Phase II proof-of-concept trial in PRCC demonstrated that c-Met positive patients (n=44) had a median PFS of 6.2 months (4.1, 7.0) compared with 1.4 months (1.4, 2.7) for c-Met negative patients (n=46), both on savolitinib. Savolitinib is currently in 13 ongoing clinical trials across papillary renal cell carcinoma (PRCC), clear cell renal carcinoma (ccRCC), non-small cell lung cancer (NSCLC), pulmonary sarcomatoid carcinoma and gastric cancer. In seven of the trials, savolitinib is being tested in combination with either durvalumab (PD-L1), Tagrisso (T790M), Iressa (EGFR) or docetaxel (chemo). For an up-to-date overview of the pipeline, see Chi-Med's website.

The HCM-AZN collaboration building value for both

At the London HCM R&D day, Susan Galbraith, senior VP IMED Oncology at AZN provided an update on savolitinib and the ongoing collaboration between HCM. AZN has a track record of development in EGFRm lung cancer and personalised healthcare, particularly with delivery of ctDNA testing under the stewardship of current CEO Pascal Soriot (ex-COO Roche, ex-CEO Genentech). AZN focuses on four main areas of cancer biochemistry: tumour drivers and resistance, DNA damage response, immunotherapy and antibody drug conjugates. These are set on a backdrop of personalised care through exploration of rational combinations. The company's expertise in developing targeted therapies in NSCLC in recent years has been underpinned by Tagrisso (osimertinib), a TKI which targets the T790M mutation that arises as acquired resistance to first-generation EGFR targeted drugs. Tagrisso took a ground-breaking two years and eight months from the start of trials to launch in its target indication. In Phase III AURA trial, Tagrisso demonstrated a median PFS of 10.1 months compared with 4.4 months for standard platinum-based chemotherapy. AZN reported $423m sales of Tagrisso in its first year.

AZN launched one of the first selective EGFR inhibitors In Iressa in 2003 and it was originally indicated for patients with locally advanced or metastatic NSCLC who progressed after chemotherapy. In 2005 following the failure of two post-approval clinical studies (no OS benefit), it was removed by the FDA from the US market. It was not until the development of a companion diagnostic (Qiagen therascreen EGFR RGQ PCR kit), which could correctly detect the patients most likely to benefit, that it was reapproved by the FDA for the particular treatment of patients with EGFR mutated advanced NSCLC (all lines of treatment). This understanding has driven AZN's approach subsequently and was recently evidenced when the approval of Tagrisso in late 2015 came with a companion diagnostic. HCM and AZN have utilised this understanding and have completed development of the savolitinib companion diagnostic assay (agreement with Foundation Medicine for its development).

Targeted therapy combinations have to date been challenging; while they offer the prospect of shutting down multiple cancer proliferation pathways or, in the case of immunotherapies stimulating multiple immune components, the compounding of side effect profiles can often be intolerable. As such, the development of cleaner compounds is needed. Savolitinib's safety profile to date

indicates that it may be useful in combination with some of AZN's marketed compounds, particularly with EGFR compounds given that MET amplification is a driver of resistance to Tagrisso/Iressa. As such, multiple trials are ongoing testing Iressa, Tagrisso and durvalumab (PD-L1) in combination with savolitinib.

Possible NDA submission for NSCLC and PRCC in 2017

New data (Phase II expansion data) from the multi-arm TATTON trial in second-line EGFR-mutant lung cancer with savolitinib in combination with osimertinib (Tagrisso) are expected shortly at ASCO 2017 and, if positive, could lead to the initiation of a global Phase III programme in H217. The initiation of the Phase II expansion triggered a $10m milestone payment from AZN to HCM in June 2016. Importantly, overwhelmingly positive data could support a US NDA under breakthrough therapy designation for the NSCLC indication (second-line in combination with Tagrisso). Phase I data presented at ESMO 2016 from the TATTON trial demonstrated that 9/17 patients with varying T790M status had a partial response and, of those who were both c-Met+ and T790M-, four had a partial response (n=4/6). Safety data published at ASCO 2015 demonstrated that there were three dose-limiting toxicities (n=12) that included fatigue (grade 3), neutropenia (grade 4) and nausea (grade 3).

In addition to savolitinib in NSCLC, positive overall survival data from the Phase II in PRCC in late 2017 (the study completed enrolment in October 2015) could enable a US NDA submission (under the breakthrough therapy designation), with potential US launch for the PRCC indication in early 2018.

Peaks sales potential of $3.4bn across current clinical indications

We forecast global peak sales for savolitinib of $3.4bn across the potential PRCC, CRCC, NSCLC and gastric cancer indications. In addition, we forecast $181m in peak sales in China (launch 2021, peak sales 2026) for a pulmonary sarcomatoid (a subsect of lung cancer); Phase II trials in C-MET +ve plus exon 14 skipping patients started in China in 2017. Exhibit 5 details savolitinib's peak sales potential assumptions. We assume pricing of $10,000 per month in the US and ROW ex-China, with China priced at a 50% discount. We believe this is conservative given that AZN's Tagrisso, a third-generation TKI, is priced at $15,000 per month in the US and $7,500 a month in China.

Exhibit 5: Savolitinib peak sales forecasts

Product	Indication	Launch year/ peak sales China	Launch year/ peak sales ROW	Assumptions
Savolitinib	PRCC	2018/2025 $128.5m	2018/2025 $474.8m	Global 2015 new cases (50,000), China 2015 new cases (7,800) C-met amplification 40-70%, therefore assume higher penetration rates. China penetration 20%, $5,000 per month, 12-month treatment duration. ROW penetration 8%, $10,000 per month, 12-month treatment duration.
	Clear cell renal carcinoma	2020/2026 $127.0m	2020/2025 $483.7m	Global 2015 new cases (270,000), China 2015 new cases (54,000) C-met overexpression 79%. China penetration 3%, $5,000 per month, 12-month treatment duration. ROW penetration 1.5%, $10,000 per month, 12-month treatment duration.
	NSCLC	2020/2027 $290.2m	2020/2025 $844.7m	Global new cases (1,690,000), China new cases (623,000) C-met amplification 10%. China penetration 0.6%, $5,000 per month, 12-month treatment duration. ROW penetration 0.5%, $10,000 per month, 12-month treatment duration. Our penetration rates reflect use in first-line (exon 14 skipping and MET amp), second-line (MET+ esp in combo with Tagrisso/Iressa) and third-line (Tagrisso failures).
	Gastric cancer	2021/2028 $325.6m	2021/2026 $742.0m	Global new cases (1,034,000), China new cases (454,000) C-met amplification 10%. China penetration 1%, $5,000 per month, 12-month treatment duration. ROW penetration 0.8%, $10,000 per month, 12-month treatment duration.
	Deal economics			Deal economics: $140m in initial upfront and milestones from AZN royalty rate 30% on China, 9-13%% ROW. COGs & SG&A on China sales only. R&D proportioned.

Source: Edison Investment Research. Note: FX rate US$1.25/£.

Sulfatinib not just a TKI

Sulfatinib is an oral angio-immunokinase inhibitor that targets VEGF1,2,3, FGFR1 and CSF-1R kinases. Until recently, its binding to CSF-1R was unknown, but new data now highlight the additional mode of action. CSF-1R (colony stimulating factor 1 receptor) is a cell surface protein that acts as the receptor for the cytokine, CSF1, a cytokine that controls macrophage (a type of white blood cells) function. Inhibition of CSF-1R limits the production of pro tumour macrophages which, among other functions, is believed to aid in angiogenesis, tumour cell invasion and evasion of the immune system. This mechanism of action could further differentiate it from other VEGFR inhibitors.

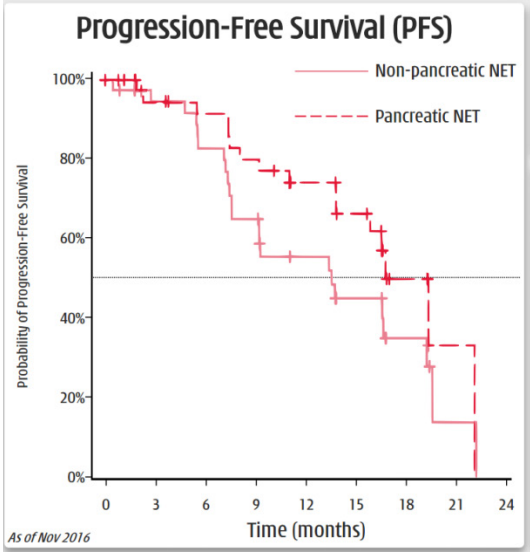
UnNET need

Neuroendocrine tumours (NETs) are cancers that arise from cells of the endocrine and nervous systems, predominately in the digestive and respiratory tracts. While the current prevalence of NET in the US is ~140,000 patients (incidence of ~19,000 new cases per year), current treatment modalities are limited to subsets of NET with no broadly effective drugs across the NET spectrum. Sulfatinib clinical data appear to demonstrate beneficial PFS over leading drugs Sutent and Afinitor; however, variances in patient demographics, trial design, disease severity and standards of care make comparisons difficult.

Targeting VEGF pathways has been proven to be of clinical benefit to patients with advanced NETs, in particular pancreatic NET. Pfizer's Sutent (sunitinib) is approved for the treatment of advanced pancreatic NET; in its Phase II registration trial (n=171; Sutent, n=86; placebo, n=85), Sutent demonstrated a median PFS of 10.2 months (95% CI: 7.4-16.9 months) versus 5.4 months on placebo (p=0.000146) and an ORR of 9.3% (95% CI: 3.2% - 15.4%) versus 0% on placebo (0.0066). Novartis's Afinitor (everolimus) is an mTOR inhibitor approved in the US for progressive GI NET, progressive lung NET and advanced pancreatic NET. In its registration trial for locally advanced or metastatic advanced pancreatic NET, Afinitor demonstrated a median PFS of 11.4 months vs 5.4 months for placebo (p-value <0.001), comparing favourably with Sutent.

In a Phase II proof-of-concept (data cut-off: 20 January 2017) trial, sulfatinib demonstrated a median PFS in 41 pancreatic NET (PNET) patients of 19.4 months (13.9- 22.1) (Exhibit 6) and an ORR of 17.1% (n=7/41), comparing favourably to Sutent and Afinitor. Importantly, in this trial sulfatinib demonstrated anti-tumour activity in patients who failed on sunitinib.

Exhibit 6: PFS and safety of sulfatinib in Phase II proof-of-concept trial



	Median PFS (months)	PDs / Deaths (% pts)
All NET (81)	16.6m (13.6, 19.4)	48.1% (39/81)
P-NET (41)	19.4m (13.9, 22.1)	39.0% (16/41)
Non-P NET (40)	13.6m (7.6, 19.3)	57.5% (23/40)

Safety - Well tolerated
- Adverse Events manageable

	Grade ≥3 (≥4pts) n (%)	Adverse Events ("AEs") - Regardless of causality	N=81 n (%)
Hypertension	25 (30.9)	Any AE	81 (100)
Proteinuria	11 (13.6)	Grade ≥3 AE	63 (77.8)
Hyperuricemia	8 (9.9)	Any SAE	21 (25.9)
Hypertri-glyceridemia	7 (8.6)	Any drug-related AE	81 (100)
		Any drug-related Gr ≥3 AE	58 (71.6)
Diarrhea	6 (7.4)		
ALT increased	5 (6.2)	Any drug related SAE	10 (12.3)
Anemia	4 (4.9)	Drug related AE leading to:	
Hypokalemia	4 (4.9)	dose interruption	40 (49.4)
Hepatic function abnormal	4 (4.9)	dose reduction	20 (24.7)
		drug withdrawal	7 (8.6)

Source: Company presentation

Safety is mixed when comparing Sutent and sulfatinib. While discontinuation rates were low for sulfatinib at 8.6% (n=81 across 41 PNET and 40 non-PNET patients) compared to Sutent (22% v 17% on placebo), overall incidence of grade 3 adverse events was higher at 71.6% vs 54% (Sutent vs 50% for placebo). Most common grade 3 and above adverse events with sulfatinib included hypertension at 30.9% (Sutent: 27%) and proteinuria 13.6%.

Registration trials define near-term value

Sulfatinib is currently in six ongoing trials (Exhibit 7); two Phase III registration trials (pancreatic-NET and extra[non]-pancreatic-NET), three Phase II trials (biliary tract carcinoma and thyroid cancer) and one Phase I crossover study in the US. A phase II US study in NET is expected to initiate by year end 2017. PFS data (top-line) from the China Phase III registration trials (SANET-p and SANET-ep) are anticipated in 2018. Positive data could lead to a China FDA filing in 2018/19. Sulfatinib is an unpartnered asset and HCM could reap the full economic benefit by launching this asset through its extensive manufacturing and distribution prescription drug business in China.

Exhibit 7: Sulfatinib clinical trial programme

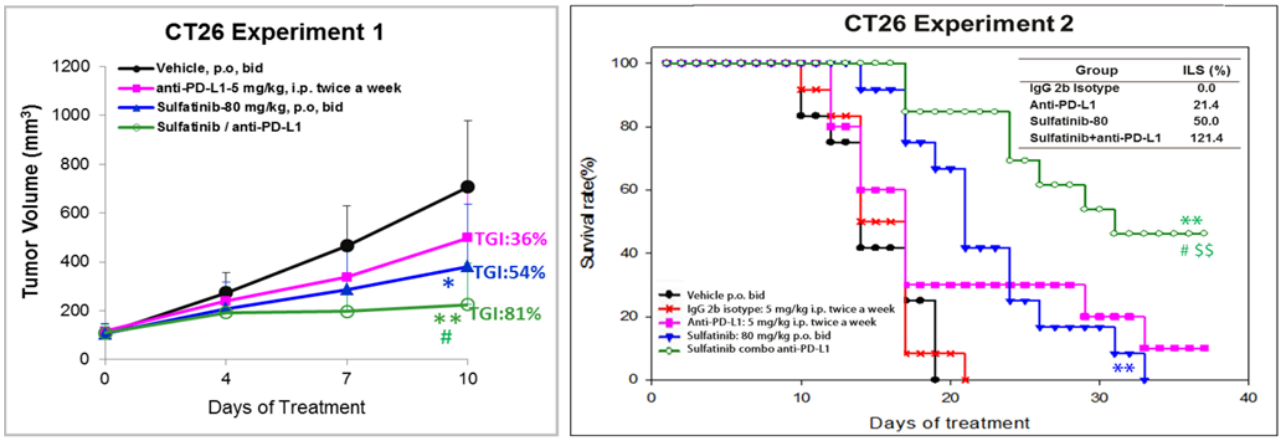
Indication	Status	Notes
Pancreatic NET	Phase III China (SANET-p)	Pancreatic neuroendocrine cancer is a cancer that originates in the endocrine cells of the pancreas. 195 patients have been enrolled, top line data on the primary endpoint of PFS are expected in 2018.
Non-pancreatic NET	Phase III China (SANET-ep)	Extra pancreatic neuroendocrine tumours arise from non-pancreatic endocrine tissue such as the gastrointestinal tract and lung/thymus, 270 patients have been enrolled, top line data on the primary endpoint of PFS are expected in 2018.
Caucasian bridging study	US-based Phase I crossover study	Currently enrolling patients. It consists of dose escalation and expansion phases. The study aims to replicate earlier trials performed in China and confirm the safety profile. Once successfully completed it could enable the quick progression into US Phase II trial in NET.
Medullary thyroid ca.	Phase II China	15 patients were enrolled with advanced medullary thyroid cancer. If at least two subjects had an objective response, a further 10 subjects were enrolled. Sulfatinib is administered daily for 28 days; primary endpoint is overall response rate with a follow-up for 16 months. Primary data are expected in 2018 with enrolment by year end.
Differentiated thyroid ca	Phase II China	15 patients with differentiated thyroid cancer. If at least two subjects had an objective response, a further 10 subjects were enrolled. Sulfatinib is administered daily for 28 days, primary endpoint is overall response rate with a follow-up for 16 months. Primary data are expected in 2018 with enrolment by year end.
Biliary tract cancer	Phase II China	The Phase II biliary tract cancer trial has begun enrolment of 16 patients who have unresectable, metastatic disease and have progressed after first-line chemotherapy, if at least four patients remain progression free in the first stage an additional 16 patients will be enrolled. Sulfatinib is administrated once a day for 28 days. The primary endpoint is the 16 week progression free survival rate. Both biliary tract and thyroid represent areas of unmet need, particularly in second- and third-line care. Primary data should be available in 2018.

Source: Company presentation, Edison Investment Research

IC combinations could be synergistic

Recent research indicates that antiangiogenic TKIs may be synergistically combined with immunotherapies to increase response rates. At AACR in April, HCM presented preclinical data on sulfatinib. A part of that data looked to study the effect a PD-L1 inhibitor in combination with sulfatinib had on survival and tumour volume in a CT26 syngeneic murine model. The combination demonstrated an 81% inhibition of tumour growth comparing favourably to the PD-L1 inhibitor (36%) and sulfatinib (54%) alone. This effect carried through to survival rates, as the combination demonstrated a c 50% survival at 35 days compared with less than 10% for either as monotherapies (Exhibit 8). Sulfatinib also has potential in other tumour types, eg breast cancer with FGFR1 activation. HCM may explore these indications in the future.

Exhibit 8: Effect sulfatinib and anti-PD-L1 has on survival and tumour volume in a CT26 syngeneic model



- **Sulfatinib combined with anti-PD-L1 displayed improved tumor growth inhibition (experiment 1) and prolonged increase life-time span (ILS) (experiment 2, 1500 mm³ was regarded as endpoint).** Difference in tumor volume change was analyzed using student t test. Survival curves were drawn by the Kaplan-Meier method and analyzed by the log-rank test. * $p<0.05$, ** $p<0.01$ vs vehicle; # $p<0.05$ vs anti-PD-L1; $^{\$\$}$, $p<0.01$ vs sulfatinib.

Source: Company presentation

Peak sales potential of $1bn across all indications

We forecast global peak sales for sulfatinib of $1bn across the NET and thyroid cancer indications. Exhibit 9 details the full clinical trial programme, penetration/incident rates and penetration assumptions. Our unchanged peak sales forecasts for sulfatinib in NET are conservative, as at this point we assess mainly the US market, given a lack of meaningful statistics for either China or ROW across the broad spectrum of NET. We have assumed a 50,000 prevalence rate in China for modelling purposes. HCM currently retains all rights to the products worldwide. While we assume the product is partnered in our modelling assumptions, commercialisation in China alone would in the longer term lead to an uplift in economic returns given the significant existing commercialisation base.

Exhibit 9: Sulfatinib peak sales forecasts

Product	Indication	Launch year/ peak sales China	Launch year/ peak sales ROW	Assumptions
Sulfatinib	NET	2019/2025 $78.8m	2020/2025 $585.8m	US prevalence 140,000, China prevalence assumption 50,000. China penetration 5%, $2,500 per month, 12-month treatment duration. US penetration 5.4%, $5,000 per month, 12-month treatment duration.
	Thyroid	2019/2024 $69.2m	2020/2024 $261.6m	Global new cases 162,000, China new cases 46,000. China penetration 4%, $2,500 per month, 12-month treatment duration. ROW penetration 4.0%, $5,000 per month, 12-month treatment duration.
	Deal economic assumptions			Deal economics: Assume $80m in upfront licence fees and milestones from a potential partner, royalty rate 30% on China, 11% ROW. COGs & SG&A on China sales only. R&D proportioned.

Source: Edison Investment Research. Note: FX rate US$1.25/£.

Epitinib NSCLC with brain metastases (BM)

Epitinib is a selective EGFR TKI designed for optimal brain penetration, to target brain metastases (BM) associated with EGFR mutation positive solid tumours. At the December 2016 IASLC World Conference on Lung Cancer, HCM presented data from its ongoing Phase Ib trial in first-line patients with EGFR+ NSCLC with brain metastasis. In terms of efficacy, clinical utility was evident in EGFR+ patients, and patients who were EGFR-treatment naïve demonstrated a strong response with an overall response rate of 61.9% and disease control rate (DCR) of 90.5%. This Phase Ib trial has been expanded into a Phase Ib/II proof-of-concept trial, which is ongoing in China; mature PFS data are expected in 2017.

HCM anticipates that a pivotal Phase III in first-line patients with EGFRm NSCLC with BM in China will be initiated by year end 2017 (the China FDA has cleared the Phase II/III clinical trial protocol). This could pave the way for international studies and a potential application for US approval under the FDA's breakthrough therapy designation. We note that at the R&D day the company had commented that a combination with fruquintinib in EGFRm+ NSCLC is worth exploring as part of epitinib global development plans. We forecast epitinib peak sales of $905m for the NSCLC with brain metastasis indication, based on a 5% penetration of the NSCLC patient population with brain metastasis (20% of the 1,690,000 global new cases of NSCLC patients worldwide, 623,000 new cases in China), $5,000 per month ex-China (50% discount on price in China) and 12 months' duration of treatment. HCM currently retains all rights to the products worldwide. Our note WCLC Positive data highlights NSCLC pipeline dated December 2016 provides an in-depth look at epitinib.

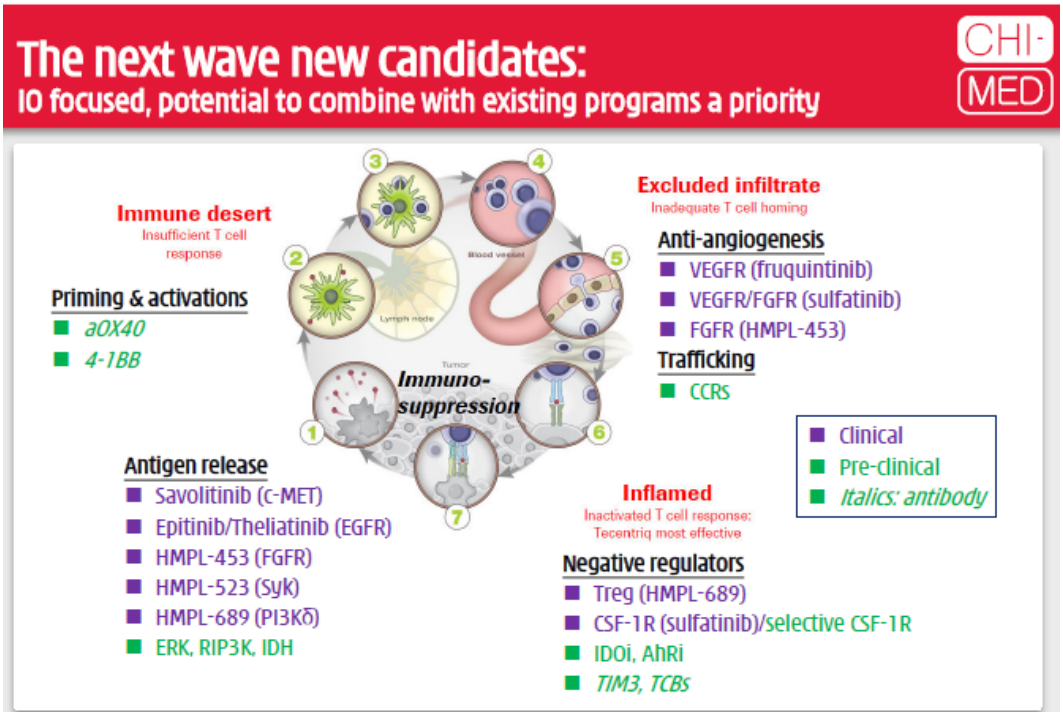
Second wave of innovation candidates

The second wave of innovation at HCM consists of candidates in dose escalation Phase I and/or those that are poised to enter phase Ib/II clinical development (POC clinical trials). These assets include theliatinib (solid tumours), HMPL-523 (cancer and immunology), HMPL-689 (blood cancer) and HMPL-453 (solid tumours). HCM hopes to generate enough data in the next 12-18 months to sufficiently demonstrate proof of concept for these compounds. Given the early-stage clinical development, these compounds contribute little or zero to our valuation of HCM, but progression into Phase II and beyond would lead to uplift in our valuation of the company. Furthermore, given the timelines to market (circa 2020 for theliatinib in its first indication, HMP-523 circa 2023), we would expect HCM to commercialise these assets alone in China and potentially in selective international markets. Exhibit 11 summarises the second-wave candidates.

Third wave: Introducing next wave of new candidates

HCM's current clinical-stage oncology pipeline targets in the main either genetic drivers (antigen release) or normalising tumour-related abnormal blood supply growth (anti-angiogenesis). The next wave of HCM programmes includes drug classes that are designed to target cancer immunity (Exhibit 10) and HCM hopes that the third wave of assets can be combined with its existing drug portfolio. Four or five programmes against novel immuno-oncology targets could enter clinical-phase development over the next three to four years. The early-stage research engine at HCM demonstrates its longer-term commitment to innovation.

Exhibit 10: The next wave of new candidates



Source: Company presentations

Exhibit 11: Second-wave pre-proof of concept pipeline

Product	Mechanism of action	Indication	Status	Notes	Development status	Development plans
Theliatinib	EGFR Wild-Type Inhibitor	Solids tumours	Phase I/Ib	Theliatinib is an oral small molecule EGFR inhibitor that has shown potent preclinical activity against tumours with EGFR-activating mutations and those without (known as wild-type). Clinical activity against wild-type tumours could address significant cancer types; particularly SCC lung, CRC, oesophageal, head and neck and breast cancer. HCM currently retains all rights to the products worldwide.	Phase I dose escalation study is expected to complete H217; data so far show that while the maxium tolerated dose (MTD has not yet been reached, drug exposures at 300mg once daily is well above exposures expected for efficacy. Phase Ib study in wild-type EGFR oesophageal tumours is enrolling.	Patient selection criteria are being worked out for other cancers including NSCLC and head and neck. A move into Phase III in China in oesophageal cancer is likely in the next year or 18 months given there are 478,000 new cases per year in China versus only 17,000 in the US) and initial Phase Ib data are looking very encouraging as mentioned in R&D briefing.
HMPL-523	Syk inhibitor	Multiple: rheumatoid arthritis, immunology, haematological cancers, lymphoma	Phase I	SYK (spleen tyrosine kinase) is a key signalling molecule in B Cell activation, proliferation, and migration implicated in malignancies and auto-immune conditions. HMPL-523 is in Phase I in rheumatoid arthritis (RA) and is also being evaluated for lymphoma. Gilead is leading the way in Syk inhibitor development; Entospletinib is currently in Phase II for haematological malignancies and AML and GS-9876 is in Phase II for rheumatoid arthritis. HCM currently retains all rights to the products worldwide.	Phase I dose escalation study has completed in healthy subjects, data disclosed at 2016 ACR conference include favourable PK data. US IND for immunology is on hold and HCM plans to submit the FDA-requested GLP toxicity data for metabolite M1 in mid-2017. Proof of concept studies in rheumatoid arthritis are planned once the FDA is satisfied with the additional data submission. Dose escalation in lymphoma patients is ongoing (Australia, China), and dose expansion is expected to initiate in H217.	In China, the focus will be on haematological malignancies with high likelihood of success and fast track registration potential. Global development plans (Australia or US) will explore novel combinations.
HMPL-689	PI3K delta inhibitor	Haematological cancers, lymphoma	Phase I	PI3K delta activation has become a proven target for B cell malignancies. HMPL-689 is a novel PI3K delta inhibitor that is being evaluated as a first in class in China and best-in-class agent globally (improved isoform selectivity, potency and PK properties). Gilead's PI3K delta inhibitor idelalisib is currently in Phase III for relapsed refractory CLL. HCM currently retains all rights to the products worldwide.	Completed Phase I dose escalation in Australia with favourable PK and safety profile, efficacious dose range defined.	China IND has been accepted and a dose escalation study in haematological cancer patients is on track to initiate in Q317. Global development plans (Australia or US) will explore novel combinations.
HMPL-453	FGFR1,2,3 inhibitor	Solids tumours	Phase I	The FGF (fibroblast growth factor) signalling pathway is increasingly implicated in tumour genesis and drug resistance. Fibroblast growth factors and their receptors tightly regulate key cell behaviours, such as proliferation, differentiation, migration, and survival. FGFR genetic alterations are oncogenic drivers. A number of anti-FGFR (selective and non-selective) compounds are in development. AstraZeneca's selective inhibitor AZ4547 is currently in Phase II for solid tumours. HCM currently retains all rights to the products worldwide.	Phase I dose escalation study (Australia) is ongoing.	China IND has been accepted and Phase I dose escalation study is expected to initiate in mid-2017.

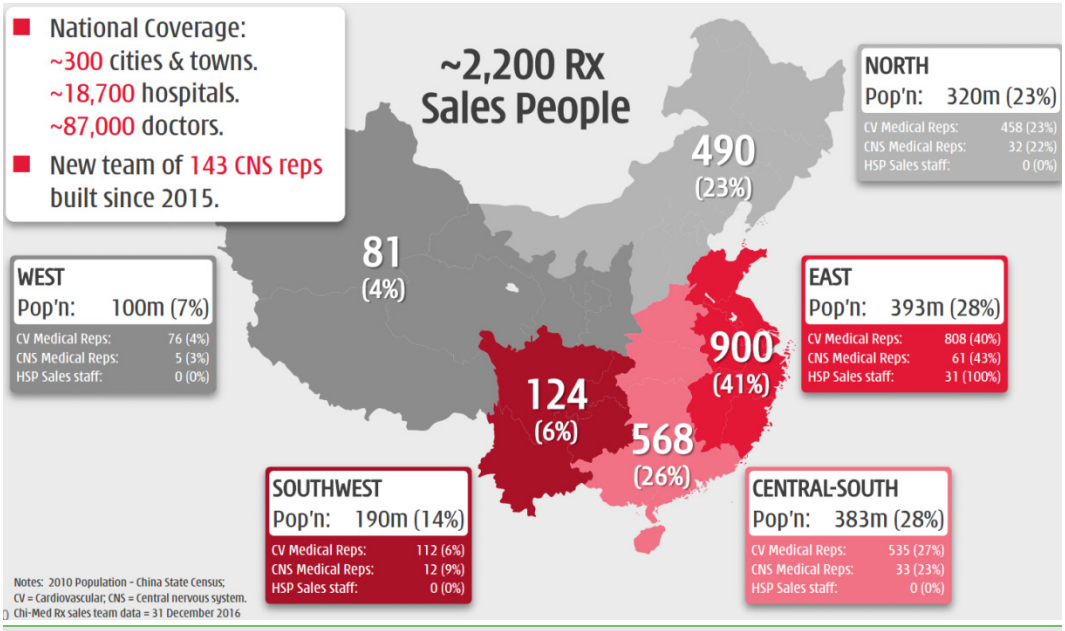
Source: Company presentations, Edison Investment Research

China Commercial Platform to leverage new assets

HCM's Commercial Platform (CP, China Healthcare business) has an established track record of commercial success; having grown from $21.9m in reported revenues in 2003 to $627.4m (non-consolidated at the group level), achieved mainly through acquisitions and in-licensing but also through organic growth. In 2016, a major source of the 180% uplift in net income attributable to HCM (FY16 $70.3m) was due to one-time property gains (2016 one-time gain of $40.4m, net of tax, from land compensation and other subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government). Core underlying net income grew 19% to $29.9m, reflecting robust growth in the prescription drug business. Profit and cash generation from the CP business continues to be utilised to aid funding research and development activities in the innovation platform division. The group's existing China business consists of 200 mature products, of which the top seven products represent 63% of sales and 92% of gross profit; these products are household brands in China, many with leadership market shares. For example, sales of SXBX for coronary artery disease grew 23% to $195.4m in 2016 (through a 50:50 mixture of price and volume increases), demonstrating the effectiveness of its commercial sales infrastructure.

Over the past 15 years, HCM has built a broad prescription drug, consumer health and over-the-counter (OTC) fully integrated, manufacturing, marketing, and distribution business under its CP business division, which reaches across multiple provinces in China (Exhibit 12). The aim has been to grow this sizeable sale and manufacturing infrastructure (currently 3,300 China sales people including 2,200 medical reps and 1,100 OTC sales people) in over 300 cities and towns to harness the considerable growth opportunities that currently exist and will arise from partnering with third parties and launching in-house developed innovative therapies. For a broader and more in-depth note on the CP business, see our note Stellar Evolution.

Exhibit 12: CP sales infrastructure in China



Source: Company presentations

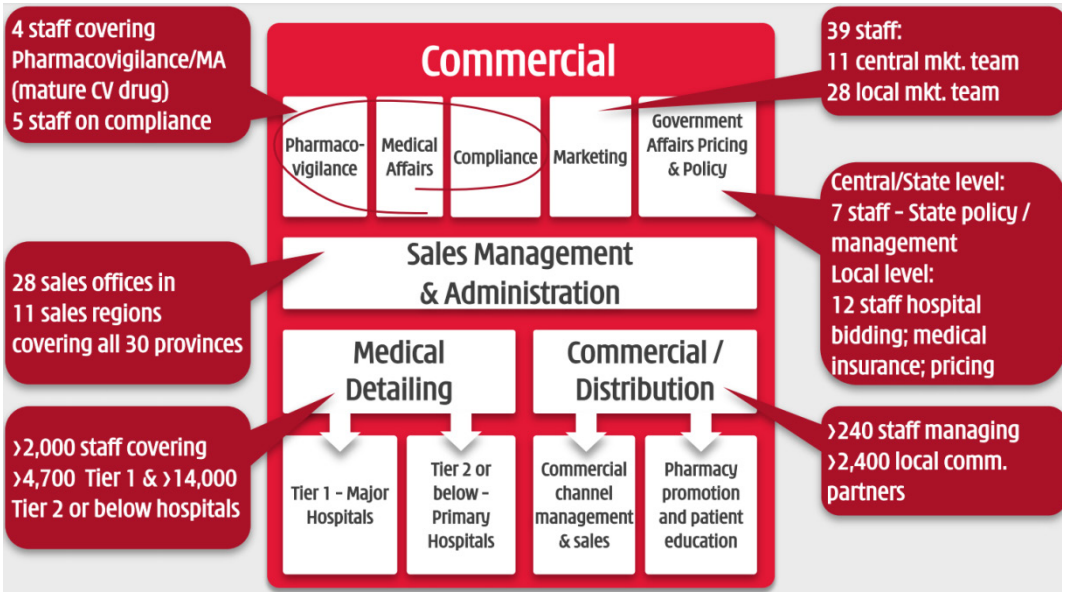
Near term, as Lilly and HCM look to launch fruquintinib into the China market (potential approval in 2018), HCM has been investing to build the required manufacturing and commercial infrastructure. The key areas that needed to be built on the manufacturing side are API (active pharmaceutical ingredient) manufacturing, and drug product formulation and packaging; in China the latter is where the manufacturing licence is held.

Fruquintinib manufacturing of commercial drug product – ready to go

API manufacturing is outsourced to large-scale contract manufacturers: Asymchem, STA and WuXi AppTec (established China-based companies that produce API for many of the large multinational pharmaceutical companies for use in China and international markets). On the formulation and packaging side, HCM has built a facility in Suzhou (designed to meet global Good Manufacturing Practice standards, which has been overseen by Eli Lilly's quality and control manufacturing division); this facility will be the commercial manufacturing site for all HCM innovation products in China (second phase of expansion is underway and this capacity will support the commercialisation of HCM's unpartnered assets). Presently the facility is ready to supply all fruquintinib commercial and clinical supply needs and thus HCM/AZN will be able to launch in China shortly after approval; all NDA work in chemistry, manufacturing and control for fruquintinib has been completed and management expects the NDA submission in July/August 2017.

In terms of the October 2013 agreement with Lilly for the co-development of fruquintinib for the Chinese market (worth up to $86.5m in upfront fees and milestones with an option for global development), Lilly is obligated to pay HCM tiered royalties (15-20%) on sales made of fruquintinib in China and Hong Kong (the rate to be determined based on the dollar amount of sales made for all products in that year). In the process of developing and selling fruquintinib, HCM has benefited from its partnership with Lilly. While on the commercial side HCM is involved in a large range of activities, HCM's CP infrastructure, particularly in commercial operations management, manufacturing and distribution, regulatory and reimbursement coverage, is well established in areas such as cardiovascular health, but is lacking in other areas of importance. Exhibit 13 highlights the complexity of the commercial business, including areas where HCM is still in the process of developing, namely pharmaco-vigilance of a launched product, medical affairs, compliance, marketing, government affairs pricing and policy etc. HCM's partnerships with Lilly and also AZN are enabling it to strengthen these areas of the business.

Exhibit 13: Commercial Infrastructure



Source: Company presentations

In time, the group intends to build a dedicated oncology and immunology sales and marketing organisation to capitalise on its unpartnered assets as it moves to become a fully integrated biopharmaceutical company in China (and eventually ex-China). Launching the higher-margin innovation platform products will significantly affect long-term operating margins given the

substantial operational leverage, although we note that in the shorter term margins would fall due to the need for increased investment and initial product launch costs.

Sensitivities

HCM is subject to the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes, partnering setbacks, and financing and commercial risks. The key sensitivities for HCM relate to crystallising value from the mid- to late-stage pipeline, in particular savolitinib, fruquintinib and sulfatinib; these three products contribute ~65 % to our valuation. For the earlier-stage pipeline, both clinical development and partnering risks remain. Economic uncertainties will always exist in China; however, we believe government measures to open up the private healthcare insurance market to international players on top of extensive (although less broad) universal state coverage should help address these concerns. Furthermore, uptake of the more expensive innovative cancer drugs is likely to be skewed to the growing and increasingly affluent middle class population. One needs only look to the luxury and branded goods sectors as a benchmark of what consumers will pay if they see a perceived benefit. Regulation and reimbursement risks are pertinent for all drug companies. Navigating the nuances of the healthcare system in China has been particularly troublesome for a number of Western companies, but HCM's local expertise stands it in good stead, as evidenced by the strong set of FY16 results.

Valuation

HCM's business diversity means the best approach to valuation is a sum-of-the-parts. The innovation platform (R&D unit) is a classic emerging biopharmaceutical play and is valued using a discounted cash flow (DCF), with the rNPV of the individual clinical projects (adjusted for the success probabilities) summed and netted against the costs of running the operation. CP is cash and profit generating, so earnings-based metrics are appropriate.

Exhibit 14: HCM sum-of-the-parts valuation

Business unit	Method	Value	Value per share	Value per ADS**
Innovation Platform	rNPV	$1,948.6m	2,570p	1,606c
Commercial Platform	P/E multiple (23.6x) on 2017e forecast of $33.4m (SHPL and HBYS JVs)*	$788.8m	1,040p	650c
Net cash at end 2016e		$56.9m	75p	47c
Minus unallocated costs	NPV	$57.7m	76p	48c
Hutchison China MediTech total		$2,736.6m	3,610p	2,256c

Source: Edison Investment Research. Note: *Equity in earnings of equity investees, net of tax. FX rate US$1.25/£. **Value per ADS is based on shares outstanding of 121,470,208, equivalent to half an ordinary share.

For the innovation platform, our DCF-based calculation of the clinical projects gives a risk-adjusted value of $1,948.6m (equivalent to 2,570p a share), with the later clinical stage of assets savolitinib, fruquintinib and sulfatinib carrying the most value (at $1,770.8m and 2,336p per share) in our model. These quickly progressing TKIs have the scope to add more value as regulatory filings and potential approval trigger milestone payments, and the probability of success alters our risk-adjusted discount rate.

Exhibit 15 details the breakdown of contribution from products by indication to our risk-adjusted NPV. However, we have included the non-risk adjusted NPV (shaded in grey) to illustrate the potential value of the pipeline should all projects in our forecasts succeed. Projects in preclinical development or early Phase I are not yet included in our valuation.

We have made some minor changes to our assumptions. For savolitinib we apply a 50% (from 75%) probability of success in NSCLC; this reflects that pivotal phase III global trial decision will be made in 2017. We now include rNPV of $36.4m for the Pulmonary Sarcomatoid cancer; as phase II trials have initiated in China. For fruquintinib we have delayed our international launch year assumptions for CRC, NSCLC and Gastric to reflect the ongoing US bridging studies and the uncertainty of timeframes of US Phase II/III trials related to Lilly's international co-development optionality. Timelines to reach our peak sales assumptions have additionally been pushed back, all else being equal our peak sales numbers has increased slightly as a function of our expected 2% price increase per annum from launch year.

Exhibit 15: Innovation platform valuation by product and indication

Product	Indication	Launch	Peak sales ($m)	Value ($m)	Probability	rNPV ($m)	rNPV/ share ($/share)	rNPV/ share (£)	rNPV/ ADS ($/ADS)	NPV/ share (£)*
savolitinib (AZD6094/volitinib)	Papillary renal cell carcinoma	2018(China) 2018 (ROW)	$129m (China) $475m (ROW)	351.0	75%**	256.8	4.2	3.4	**2.1**	**4.6**
	Clear cell carcinoma	2020 (China) 2020 (ROW)	$127.0m (China) $484m (ROW)	265.2	75%	198.0	3.3	2.6	**1.6**	**3.5**
	NSCLC	2020 (China) 2020 (ROW)	$290m (China) $845m (ROW)	408.1	50%**	203.0	3.3	2.7	**1.7**	**5.4**
	Gastric cancer	2021 (China) 2021 (ROW)	$326m (China) $742m (ROW)	342.4	35%	117.0	1.9	1.5	**1.0**	**4.5**
	Pulmonary sarcomatoid cancer	2021 (China)	$181m (China)	75.0	50%	36.4	0.6	0.5	**0.3**	**1.0**
fruquintinib	CRC	2018 (China) 2021 (ROW)	$106m (China) $655m (ROW)	307.9	75%	230.4	3.8	3.0	**1.9**	**4.1**
	NSCLC	2020 (China) 2021 (ROW)	$298m (China) $721m (ROW)	327.6	75%	245.7	4.1	3.2	**2.0**	**4.3**
	Gastric cancer	2019 (China) 2021 (ROW)	$142m (China) $392m (ROW)	253.4	75%	190.1	3.1	2.5	**1.6**	**3.3**
Sulfatinib	NET	2019 (China) 2020 (ROW)	$78.8m (China) $586m (ROW)	240.6	75%	180.5	3.0	2.4	**1.5**	**3.2**
	Thyroid cancer	2019 (China) 2020 (ROW)	$69m (China) $262m (ROW)	225.9	50%	112.9	1.9	1.5	**0.9**	**3.0**
Epitinib	NSCLC	2020 (China) 2020 (ROW)	$198m (China) $707m (ROW)	390.1	30%	117.0	1.9	1.5	**1.0**	**5.1**
Theliatinib	Oesophageal cancer Phase Ib	2020 (China) 2020 (ROW)	$328m (China) $149.0m (ROW)	225.2	10%	22.5	0.4	0.3	**0.2**	**3.0**
HMPL 523	RA Phase Ib	2023	$1.6bn (Global)	383.3	10%	38.3	0.6	0.5	**0.3**	**5.1**
Valuation of IP only				$3,795.6		$1,948.6	$32.13	£25.70	**$16.06**	**£50.07**

Source: Edison Investment Research. Note: *Non-risk adjusted NPV per share assumes 100% probability of success. **Probability reflects likely filing with Phase II data for breakthrough therapy designation. FX rate US$1.25/£.

With the commercial platform, we look at the earnings multiples of peers quoted on the Chinese stock exchanges (Exhibit 16). Using a 23.6x multiple (in line with the sector average for comparable domestic Chinese companies) on the 2017 forecast net attributable profit of $33.4m for the CP unit results in a valuation of $788.8m (1,040p per share). Adding net cash reported at December 2016 of $56.9m (75p a share) and subtracting unallocated corporate costs (valued using an NPV) of $57.7m (76p a share) results in our sum-of-the-parts valuation of $2,736.6m (3,610p a share). At the JV level, not consolidated by the group, Hutchison Baiyunshan, Shanghai Hutchison and Nutrition Science Partners had cash and equivalents of $91.0m at the end of December 2016. This cash is not included in our valuation of HCM.

Exhibit 16: Peers quoted on the Chinese stock exchanges

Company	Code	Net sales ($m)				Net profit ($m)				2016 Margin (%)	Valuation metrics		
		2014	2015	2016	Growth 2015-16 (%)	2014	2015	2016	Growth 2015-16 (%)		Market cap ($m)	2016 P/E (x)	2017 P/E (x)
Tianjin Zhong Xin Pharm	600329 ch	1021	1020	888	(14.90)	51.88	65.46	61.26	(6.87)	6.42	1,694	11.68	24.11
Livzon Pharmaceutical	000513 ch	794	948	1092	13.17	74.82	90.29	113.74	20.62	9.52	3,417	35.45	27.32
KPC Pharmaceuticals	600422 ch	622	708	733	3.47	41.88	61.03	59.06	(3.34)	8.63	1,358	37.31	18.12
Dong-E-E-Jiaoco Ltd-A	000423 ch	574	781	906	13.81	198.02	235.65	268.63	12.28	30.18	6,066	21.05	19.60
Zhejiang Conba Pharmaceutical-A	600572 ch	513	761	862	11.73	80.10	63.86	63.96	0.16	8.39	2,450	47.71	24.93
Jiangzhong Pharmaceutical-A	600750 ch	406	373	222	(68.34)	38.41	53.22	55.07	3.36	14.27	1,542	28.93	21.74
Jinling Pharmaceutical-A	000919 ch	400	465	516	9.92	28.59	30.18	26.12	(15.52)	6.49	873	41.66	20.15
Guizhou Yibai Pharmaceutical-A	600594 ch	450	471	526	10.41	69.38	27.46	55.81	50.79	5.83	1,837	88.67	23.88
Jiangsu Kanion Pharmaceutical-A	600557 ch	366	402	427	5.70	46.35	52.54	54.20	3.05	13.06	1,508	35.24	23.33
Zhuzhou Qianjin Pharmaceutical-A	600479 ch	315	351	411	14.46	15.24	13.48	21.67	37.79	3.84	805	72.06	32.67
Average		546	628	658	(0.06)	64.47	69.32	77.95	10.23	10.66	2,155	41.98	23.59

Source: Bloomberg. Note: Priced at 2 May 2017. Exchange rate CNY0.1533/US$ at 2 May 2017.

Financials: Healthy cash outlook

The change of reporting from IFRS to US GAAP in 2015 had a significant impact on the historical consolidated financial statements before the restated years of 2013 and 2014. This includes two main changes. First, revenue recognition of upfront and milestone payments under US GAAP is now recorded in its entirety when received as opposed to a percentage of completion method to recognise milestones under IFRS. Second, the accounting treatment of HCM's redeemable convertible shares under US GAAP means these will be classified as mezzanine equity.

At the FY16 results, revenue from continuing operations grew by 21% from $178.2m to $216.1m, with the IP division contributing $35.2m (largely attributable from payments by partners including $26.4m of licence revenues) and consolidated CP sales contributing $180.9m. We forecast IP revenues of $38.0m in 2017 and $53.3m in 2018 largely driven by developmental milestone payments from partners AZN and Lilly for progress of savolitinib and fruquintinib respectively. We expect CP to continue posting stable growth and forecast $196.2m in 2017 and $209.3m in 2018 respectively. These CP revenue numbers do not take into account revenues reported by the Shanghai Hutchison and Hutchison Baiyunshan joint ventures. Only the net attributable profit of the JV contribution is reported as equity in earnings of equity investees, net of tax below the PBT line. In 2016, this was reported as $66.2m (of which $40.4m represented property compensation gains). We forecast this to grow to $41.0m in 2017 and $35.2m in 2018; a component of this is the distribution of profits from the land compensation, which we book as $15m in 2017 and $8m in 2018. Importantly, net attributable profit of the JV contribution also includes a negative contribution from the Nestlé JV (NSP), which is not recording revenues at present but is investing around $7-8m a year for the development of HMPL-004 (reformulation to enter Phase I trials in 2017). Exhibit 17 details the historic and forecast breakdown of CP revenues and profit. Note that the revenue and net profit breakdown includes all subsidiaries and 100% of the JV contribution. However, under US GAAP only the net profit/(loss) attributable to HCM is recorded in the consolidated P&L at PBT level. PBT at the HCM consolidated level therefore includes contributions from the consolidated CP subsidiaries, the innovation platform segment and unallocated costs.

Profit before tax at the group level was a loss of $47.4m in 2016, largely due to the increase in R&D ($66.9m in 2016 versus $47.4m in 2015), S&M ($18.0m in 2016 versus $10.2m in 2015) and administrative expenses ($21.6m in 2016 versus $19.6m in 2015). We expect R&D expenses to

increase to $85.0m and $89.5m in 2017 and 2018, reflecting the substantial need for investment in the burgeoning clinical trial programmes across the IP division. We expect S&M and admin costs to increase marginally and, given higher cost assumptions, we forecast operating losses of $52.3m in 2017 and $35.4m in 2018. In 2016 net income from continuing operations, which includes the profit contribution from JVs (see above), was reported at $14.6m and we forecast losses of $15.1m in 2017 and $4.8m in 2018. After stripping out minorities, we forecast net losses attributable to the company of $21.1m in 2017 and $9.7m in 2018.

HCM retains a healthy gross cash position. At year-end 2016 there was $103.7m in cash and cash equivalents and short-term investments, offset by $46.8m in bank loans at the group level. Cash in 2016 benefited from the net $95.9m proceeds of the NASDAQ listing in March 2016. At the JV level, not consolidated by the group, Hutchison Baiyunshan, Shanghai Hutchison and Nutrition Science Partners had cash and equivalents of $91.0m (JVs have no bank borrowings to offset) at the end of December 2016. Additionally, the group has access to $70m in unutilised banking facilities.

Exhibit 17: Commercial Platform breakdown and reconciliation to group net income

US$m	2014	2015	2016	2017e	2018e	2019e
Commercial Platform						
Sales of subsidiaries and JV's *	465.4	518.9	627.3	702.9	779.4	836.9
Prescription drugs	204.9	286.6	372.2	419.1	468.9	502.9
Consumer Health	260.5	232.3	255.1	283.8	310.6	334.1
Net profit/(loss)subsidiaries and JV's, after tax	48.8	54.1	63.3	71.4	76.8	82.8
Prescription drugs	26.5	31.9	41.4	47.2	51.9	56.8
Consumer Health	22.3	22.2	21.9	24.2	25.0	26.0
Consolidated Net profit/(loss) after tax attributable to the group **	22.8	25.2	29.9	33.4	34.8	37.6
Prescription drugs	13.2	15.9	20.7	23.9	24.9	27.1
Consumer Health	9.6	9.3	9.2	9.5	9.9	10.5
Net profit/(loss) attributable to HCM before NCI (SHPL &HBYS)	23.6	26.4	30.0	33.9	35.2	38.1
Prescription drugs	13.2	15.7	19.8	23.9	24.9	27.1
Consumer Health	10.4	10.7	10.2	10.0	10.3	11.0
NSP Net profit/(Loss) attributable, Net of tax	(8.4)	(3.8)	(4.2)	(7.0)	(8.0)	(12.0)
Equity in earnings of equity investees, net of tax ****	15.2	22.6	25.8	25.9	26.1	25.9
PBT at the HCM consolidated level ***	(20.0)	(10.5)	(47.4)	(53.8)	(36.9)	(17.1)
Taxation	(1.3)	(1.6)	(4.3)	(3.2)	(3.0)	(3.4)
Equity in earnings of equity investees, net of tax ****	15.2	22.6	25.8	25.9	26.1	25.9
Equity in earnings or equity investees, net of tax, from property compensation*****	0.0	0.0	40.4	15.0	8.0	0.0
Net Income from continuing operations	(6.1)	10.4	14.5	(16.1)	(5.9)	5.4
Net Income from discontinued operations	2.0	0.0	0.0	0.0	0.0	0.0
Net Income (reported)	(4.1)	10.4	14.6	(15.1)	(4.8)	5.6
Minority interest	(3.2)	(2.4)	(2.9)	(6.0)	(4.9)	(3.7)
Net Income (reported) attributable to the company	(7.3)	8.0	11.7	(21.1)	(9.7)	1.9

Source: HCM, Edison Investment Research. Notes: *Includes unconsolidated sales from JVs. **Consolidated numbers includes JV contribution. ***Includes consolidated CP and IP and unallocated costs. ****Includes SHPL, HBYS and NSP. *****Property compensation received at the JV level and shared proportionally.

Property windfalls aid additional cash injections; the appreciation in land values has benefited the SHPL and HBYS old factory sites in Shanghai and Guangzhou, which are now in prime residential locations. The group received $105m total cash compensation at the JV level for the SHPL sites from the Shanghai government over 2015 and 2016. Further compensations are anticipated for the Guangzhou sites and we include minor contributions in our 2017 and 2018 forecasts, erring on the side of conservatism due to the uncertainty of the timing and outcome of any deal. HCM's share of this should feed in through special dividends over a number of years and we forecast an increase in dividends received from equity investees in 2017 to $50m from $30.5m in 2016.

Exhibit 18: Financial summary

	2014	2015	2016	2017e	2018e	2019e
December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue	87,329	178,203	216,080	234,199	262,526	304,619
Cost of Sales	(58,849)	(110,777)	(156,328)	(158,810)	(161,601)	(171,066)
Gross Profit	28,480	67,426	59,752	75,389	100,925	133,554
Research and development	(29,914)	(47,368)	(66,871)	(85,000)	(89,500)	(100,000)
Other overheads	(16,825)	(29,829)	(39,578)	(42,699)	(46,858)	(49,946)
EBITDA	(16,994)	(7,756)	(44,264)	(48,575)	(30,933)	(11,062)
Operating Profit (before amort. and except.)	(18,259)	(9,771)	(46,697)	(52,310)	(35,433)	(16,392)
Intangible Amortisation	0	0	0	0	0	0
Operating Profit	(18,259)	(9,771)	(46,697)	(52,310)	(35,433)	(16,392)
Net Interest	(957)	(953)	(1,129)	(1,500)	(1,500)	(659)
Exceptionals	0	0	0	0	0	0
Profit Before Tax (norm)	(19,957)	(10,540)	(47,356)	(53,810)	(36,933)	(17,051)
Profit Before Tax (reported)	(19,957)	(10,540)	(47,356)	(53,810)	(36,933)	(17,051)
Tax	(1,343)	(1,605)	(4,331)	(3,229)	(3,000)	(3,410)
Equity investments, after tax	15,180	22,572	66,244	41,900	35,150	26,100
Profit After Tax (norm)	(6,120)	10,427	14,557	(15,138)	(4,783)	5,638
Profit After Tax (reported)	(6,120)	10,427	14,557	(15,138)	(4,783)	5,638
Minority	(3,220)	(2,434)	(2,859)	(6,000)	(4,900)	(3,700)
Discontinued operations	2,034	0	0	0	0	0
Net profit (norm)	(9,340)	7,993	11,698	(21,138)	(9,683)	1,938
Net profit (reported)	(7,306)	7,993	11,698	(21,138)	(9,683)	1,938
Average Number of Shares Outstanding (m)	52.6	54.7	59.7	60.6	60.6	60.6
EPS - normalised (c)	(17.8)	14.6	19.6	(34.9)	(16.0)	3.2
EPS - normalised and fully diluted (c)	(17.8)	14.6	19.5	(34.9)	(16.0)	3.2
EPS - (reported) (c)	(13.9)	14.6	19.6	(34.9)	(16.0)	3.2
Average number of ADS outstanding (m)	105.1	109.3	119.4	121.3	121.3	121.3
Earnings per ADS - normalised ($)	(0.09)	0.07	0.10	(0.17)	(0.08)	0.02
Earnings per ADS ($)	(0.07)	0.07	0.10	(0.17)	(0.08)	0.02
BALANCE SHEET						
Fixed Assets	120,992	140,087	175,057	173,222	183,872	184,642
Intangible Assets	4,096	3,903	3,606	3,419	3,194	2,928
Tangible Assets	7,482	8,507	9,954	16,406	22,131	27,067
Investments	109,414	127,677	161,497	153,397	158,547	154,647
Current Assets	89,842	89,675	167,380	149,834	135,700	142,406
Stocks	4,405	9,555	12,822	12,000	14,000	14,060
Debtors	27,924	38,628	49,349	51,838	76,659	93,231
Cash	38,941	31,949	79,431	60,218	33,533	23,607
St investments	12,179	0	24,270	24,270	10,000	10,000
Other	6,393	9,543	1,508	1,508	1,508	1,508
Current Liabilities	(75,299)	(81,062)	(95,119)	(91,581)	(95,581)	(99,418)
Creditors	(20,427)	(24,086)	(35,538)	(32,000)	(36,000)	(39,837)
Short term borrowings	(26,282)	(23,077)	(19,957)	(19,957)	(19,957)	(19,957)
Other	(28,590)	(33,899)	(39,624)	(39,624)	(39,624)	(39,624)
Long Term Liabilities	(37,584)	(46,415)	(43,258)	(43,258)	(43,258)	(43,258)
Long term borrowings	(26,923)	(26,923)	(26,830)	(26,830)	(26,830)	(26,830)
Other long term liabilities	(10,661)	(19,492)	(16,428)	(16,428)	(16,428)	(16,428)
Net Assets	97,951	102,285	204,060	188,217	180,733	184,372
Minority	(17,764)	(18,921)	(19,790)	(25,790)	(30,690)	(34,390)
Shareholder equity	80,187	83,364	184,270	162,427	150,043	149,982
CASH FLOW						
Operating Cash Flow	8,359	(9,385)	(9,569)	(8,508)	(28,254)	2,073
Net Interest	0	0	0	0	0	0
Tax	0	0	0	0	0	0
Capex	(3,729)	(3,324)	(4,327)	(10,000)	(10,000)	(10,000)
Acquisitions/disposals	689	0	0	0	0	0
Dividends	(1,179)	(590)	(564)	(700)	(2,700)	(2,000)
Equity financing and capital movements	5,860	(1,676)	97,076	0	0	0
Other	(12,179)	12,179	(29,270)	0	14,270	0
Net Cash Flow	(2,179)	(2,796)	53,346	(19,208)	(26,684)	(9,927)
Opening net debt/(cash and ST investments)	4,645	2,085	18,051	(56,914)	(37,701)	3,254
Increase/(decrease) in ST investments	12,179	(12,179)	24,270	0	(14,270)	0
Other	(7,440)	(991)	(2,651)	(5)	0	0
Closing net debt/(cash and ST investments)	2,085	18,051	(56,914)	(37,701)	3,254	13,180

Source: Hutchison China MediTech reports, Edison Investment Research. Note: Equity investments after tax include the net profit contribution from JVs.

EDISON

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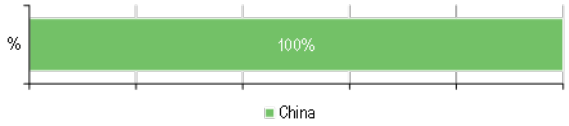
21st Floor, Hutchison House, 10 Harcourt Road, Hong Kong +852 2121 8281 www.chi-med.com	

Management team

Chairman: Simon To

Simon To is managing director and founder of Hutchison Whampoa (China), with over 30 years' service, having built up the business from a small trading company to a large investment group with interests in aviation, hotels, port logistics, consumer products, residential developments, power plants and transport infrastructure. He is chair or director of a number of China-focused businesses and joint ventures. He has a BSc in mechanical engineering from Imperial College and an MBA from Stanford University.

CEO: Christian Hogg

Christian Hogg joined the company in 2000 and, as CEO, has led all aspects of the creation, implementation and management of HCM's strategy and operations in both the innovation and commercial platforms and the London and New York IPOs. This included establishing research collaborations with AstraZeneca and Lilly and operating joint ventures with Nestlé, Hain Celestial, Shanghai Pharmaceuticals, Guangzhou Pharmaceuticals and Sinopharm. Previously he spent 10 years with Procter & Gamble, including managing the detergent business in China and the global bleach business. He has a BSc in civil engineering from Edinburgh and an MBA from the University of Tennessee.

CFO: Johnny Cheng

Johnny Cheng has been CFO since 2008. Previously he was VP finance of Bristol-Myers Squibb in China and a director of Sino-American Shanghai Squibb Pharmaceuticals and BMS (China) Investment Co. He also spent eight years in various financial positions with Nestlé China, and was an auditor with PwC (Australia) and KPMG (Beijing). He has a bachelor of economics from the University of Adelaide and is a member of the Institute of Chartered Accountants in Australia.

CSO: Weiguo Su

Weiguo Su is chief scientific officer, with 12 years' experience at the company. He created HCM's R&D strategy Innovation Platform and led all pipeline discovery. Previous experience includes director of medicinal chemistry at Pfizer. He spent seven years at Harvard under E.J. Corey, the Nobel Prize-winning medicinal chemist. Weiguo was one of the first mainland Chinese to be granted a scholarship to study at Harvard.

Principal shareholders	(%)
Hutchison Healthcare Holdings	60.37%
Mitsui & Co	5.29%
FIL	4.22%
Slater Investments	3.79%

Companies named in this report

AstraZeneca (LON:AZN), Hutchison Whampoa (HK:13), Nestlé SA (VX:NESN), Guangzhou Baiyunshan (SHE: 000522), Shanghai Pharmaceuticals (SHA: 601607), Eli Lilly (LLY US)

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