

# Chi-Med Reports 2019 Interim Results and Provides Updates on Key Clinical Programs

**London: Tuesday, July 30, 2019:** Hutchison China MediTech Limited ("Chi-Med") (AIM/Nasdaq: HCM) today announces its unaudited financial results for the six months ended June 30, 2019 and provides updates on key clinical programs. Major highlights include:

- Positive surufatinib China Phase III study in non-pancreatic neuroendocrine tumors ("NET") Interim analysis of SANET-ep study confirmed to have met primary endpoint and the Independent Data Monitoring Committee ("IDMC") recommended the study be un-blinded, a year ahead of schedule. New Drug Application ("NDA") is now being prepared for submission during 2019;
- Early progress on Elunate<sup>®</sup> (fruquintinib capsules) with China in-market sales in colorectal cancer ("CRC") of \$11.4 million<sup>1</sup> (RMB77.1 million) during H1 2019; Discussions in progress for potential inclusion in the China National Reimbursement Drug List ("NRDL") at the next update in Q4 2019;
- Potential for first savolitinib NDA targeted for H1 2020 for MET<sup>2</sup> Exon 14 deletion non-small cell lung cancer ("NSCLC") in China. Oral presentations of savolitinib data made at scientific conferences in H1 2019 in lung cancer (monotherapy and combination with Tagrisso<sup>®</sup>) and kidney cancer (combination with Imfinzi<sup>®</sup>).

Video webcast presentation at 9:00 a.m. BST and additional conference call at 9:00 a.m. EDT.

"Chi-Med's business is progressing well on all fronts." said Simon To, Chairman, Chi-Med. "All major clinical readouts in the first half were encouraging, with the stand-out results being surufatinib's positive Phase III outcome in non-pancreatic NET and savolitinib's preliminary data in MET Exon 14 deletion NSCLC along with the completion of enrollment of its registration study. We believe these accomplishments have the potential to support Chi-Med's next two NDA submissions, surufatinib later this year and savolitinib early next year."

"Highly encouraging preliminary data was also reported for the savolitinib / Tagrisso<sup>®</sup> combination in NSCLC, which led to the initiation of a global registration intent trial by AstraZeneca AB (publ) ("AstraZeneca"), the SAVANNAH study, early this year. Also, recently released preliminary data for the savolitinib / Imfinzi<sup>®</sup> combination in kidney cancer is promising."

"Our first approved oncology drug, Elunate<sup>®</sup>, is making progress, with first six-month revenue well ahead, at the same stage, of the five small molecule VEGFR<sup>3</sup> inhibitors previously launched by multinational companies in China. In our view, with time and inclusion in the China NRDL, Elunate<sup>®</sup>'s well documented efficacy and safety profile will make it a formidable competitor."

"Business is as usual for our Commercial Platform, which generated 9% net income growth on a CER<sup>4</sup> basis versus same period last year. This income helps significantly to fund our clinical development programs as well as our discovery engine which produced yet another exciting oncology asset, our ninth, with the IND<sup>5</sup> submission of our novel IDH 1/2 inhibitor<sup>6</sup> HMPL-306."

"Our organization is expanding rapidly, with our New Jersey-based international clinical and regulatory team scaling up to manage global registration studies on surufatinib and fruquintinib and early development on our B-cell malignancy assets. Our in-house oncology commercial team in China is also growing fast, managing medical affairs and getting ready for the potential launch of surufatinib late next year."

"Looking ahead at the next two years, we expect to accelerate our transformation into a fully integrated and globally-facing biopharmaceutical company with capability to discover, develop and launch multiple novel drug innovations aimed at addressing a broad range of unmet medical needs and benefiting a large number of patients."

# FINANCIAL HIGHLIGHTS

The items below are selected financial data for the six months ended June 30, 2019. All monetary figures are expressed in U.S. dollars unless otherwise stated. For more details, please refer to "Financial Review", "Operations Review" and "Interim Unaudited Condensed Consolidated Financial Statements" below.

# **OVERALL GROUP:** sufficient resources to reach multiple value inflection points on our pipeline

- Group revenue \$102.2 million (H1-18: \$102.2m).
- Net loss attributable to Chi-Med of \$45.4 million (H1-18: net loss of \$32.7m).
- Adjusted Group net cash flows (non-GAAP) was -\$63.7 million in H1 2019 including the repayment of a total of \$26.9 million in bank loans, leaving the Group with no outstanding bank borrowings. Cash from our Commercial Platform, as well as payments received from our multinational partners, continued to offset a material part of our research and development ("R&D") expenses.
- **Cash resources of \$383.6 million** at Group level as of June 30, 2019 (December 31, 2018: \$420.3m), including cash, cash equivalents and short-term investments of \$237.3 million (December 31, 2018: \$301.0m) and unutilized bank facilities of \$146.3 million (December 31, 2018: \$119.3m).

# **INNOVATION PLATFORM:** increased investment in R&D driven by expansion of our organization, operations and progress on our clinical development pipeline

- **Consolidated revenue was \$12.0 million** (H1-18: \$13.6m) mainly due to payments from AstraZeneca and Lilly. During H1 2019, following the launch of Elunate<sup>®</sup> in late 2018, we recorded \$5.5 million (H1-18: \$1.1m) in manufacturing and service fee revenues as well as royalty income from Lilly.
- **R&D expenses on an as adjusted (non-GAAP) basis increased to \$74.5 million** (H1-18: \$66.7m), primarily driven by the progress in the development of our eight clinical drug candidates, five of which are either in or about to start development outside China; the ramp-up of our small molecule manufacturing operations in Suzhou; expansion of U.S. and international clinical and regulatory operations; and establishment of our oncology commercial infrastructure in China.
- Net loss from our Innovation Platform attributable to Chi-Med of \$63.8 million (H1-18: net loss of \$52.9m).

# **COMMERCIAL PLATFORM:** solid net income growth on a CER basis due to continued progress in our Prescription Drugs business

- Total consolidated sales grew 2% (7% at CER) to \$90.2 million (H1-18: \$88.6m) mainly due to progress on our Prescription Drugs subsidiary Hutchison Sinopharm<sup>7</sup> being partially offset by rationalization of certain low contribution products in the Consumer Health business.
- Total sales of non-consolidated joint ventures increased 2% (8% at CER) to \$276.9 million (H1-18: \$271.7m) driven by solid performance on our leading prescription cardiovascular drug, She Xiang Bao Xin ("SXBX") pill, which grew 9% (15% at CER) to \$141.0 million (H1-18: \$129.8m).
- Total consolidated net income from our Commercial Platform attributable to Chi-Med increased 3% (9% at CER) to \$27.7 million (H1-18: \$26.9m).

*U.K. Analysts Meeting and Webcast Scheduled Today at 9:00 a.m. BST (4:00 p.m. HKT)* – at Citigate Dewe Rogerson, 8th Floor, Holborn Gate, 26 Southampton Buildings, London WC2A 1AN, UK. Investors may participate in the call at +44 20 3003 2666 (800 900 476 toll free in Hong Kong), or access a live video webcast of the call via Chi-Med's website at <u>www.chi-med.com/investors/event-information/</u>.

**U.S. Conference Call Scheduled Today at 9:00 a.m. EDT** – to participate in the call from the U.S., please dial 1 866 966 5335.

Additional dial-in numbers are also available at Chi-Med's website. For both calls please use conference ID "Chi-Med."

<sup>[5]</sup> Investigational New Drug ("IND");

<sup>&</sup>lt;sup>[1]</sup> In-market sales figures for Elunate® are based on information provided by Eli Lilly and Company ("Lilly");

<sup>&</sup>lt;sup>[2]</sup> mesenchymal epithelial transition receptor ("MET");

<sup>&</sup>lt;sup>[3]</sup> Vascular endothelial growth factor receptor ("VEGFR");

<sup>&</sup>lt;sup>[4]</sup> Constant Exchange Rate ("CER"). Certain financial information in this announcement is presented on a constant exchange rate basis, or at CER. These financial measures are not prepared in accordance with U.S. generally accepted accounting principles (GAAP) because they remove the effects of currency movements from our reported results. Please refer to "Use of Non-GAAP Financial Measures and Reconciliation" below for further information relevant to the interpretation of these financial measures to the most comparable GAAP measures;

<sup>&</sup>lt;sup>[6]</sup> Isocitrate dehydrogenase ("IDH") 1 and 2;

<sup>&</sup>lt;sup>[7]</sup> Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited ("Hutchison Sinopharm").

# **OPERATING HIGHLIGHTS**

The points below summarize some of Chi-Med's operating highlights so far this year. For more details, please refer to "Operations Review" below.

# SURUFATINIB (HMPL-012 or sulfatinib) – angio-immuno kinase inhibitor of VEGFR 1/2/3, fibroblast growth factor receptor ("FGFR") 1, and colony stimulating factor-1 receptor ("CSF-1R"):

- **Positive China Phase III in non-pancreatic NET:** An interim analysis in June 2019 confirmed that the Phase III non-pancreatic NET (SANET-ep) study met its primary endpoint of progression-free survival ("PFS"). As a result, the IDMC recommended the study be un-blinded, a year ahead of schedule, and preparations are now underway for an NDA submission in late 2019 for this indication in China;
- **Initiated China Phase II/III in biliary tract cancer ("BTC"):** Based on preliminary Phase Ib/IIa data, we initiated a Phase IIb/III registration study in BTC in China in March 2019; and
- Initiated PD-1 combination development: Received China IND clearance during early 2019 and initiated a Phase I safety run-in study in China of surufatinib plus Tuoyi<sup>®</sup>, an approved PD-1 monoclonal antibody from Shanghai Junshi Biosciences Co. Ltd. ("Junshi").

# FRUQUINTINIB – highly selective tyrosine kinase inhibitor ("TKI") of VEGFR 1/2/3 – potential best-inclass in terms of both efficacy and safety:

- Early progress on Elunate<sup>®</sup> (fruquintinib capsules) in third-line CRC in China:
  - **\$11.4 million (RMB77.1 million) in sales during H1 2019:** In-market sales of Elunate<sup>®</sup> to third-parties, as provided by Lilly, in the first full six-month period since its November 25, 2018 launch;
  - **Progress in reimbursement discussion:** Elunate<sup>®</sup> was included in the Shanghai provincial reimbursement drug list ("RDL") in June 2019. Discussions now in-progress for potential inclusion in the China NRDL at the next update in early Q4 2019.
- Cleared Phase III interim analysis in second-line gastric cancer: In April 2019, we conducted an interim analysis of the FRUTIGA study in China for futility. The analysis evaluated PFS and overall survival ("OS") trends after six months of therapy for the first 100 patients in the study. The IDMC recommended to continue the study without changes; and
- Initiated PD-1 combination development: Received China IND clearance in early 2019 and initiated a Phase I study of fruquintinib plus Tyvyt<sup>®</sup>, an approved PD-1 monoclonal antibody from Innovent Biologics (Suzhou) Co. Ltd. ("Innovent"). Phase I development of fruquintinib plus genolimzumab, a PD-1 monoclonal antibody under development by Genor Biopharma Co. Ltd. ("Genor") is also now underway.

# SAVOLITINIB – potential first-in-class selective MET inhibitor in late-stage clinical development:

- Reached enrollment goal in Phase II registration study MET Exon 14 deletion NSCLC: Encouraging interim data, for 31 evaluable patients, for the China Phase II registration study in MET Exon 14 deletion NSCLC were presented during the 2019 American Association for Cancer Research ("AACR") Annual Meeting. We have now reached our enrollment goal for this Phase II registration study, and subject to clinical outcome, with potential to be our first NDA submission for savolitinib in early 2020;
- AstraZeneca collaboration, leading global position in EGFR-TKI resistant NSCLC:
  - 56% objective response rate ("ORR") and 7.1 months' median duration of response in patients with acquired resistance to Iressa® or Tarceva® driven by MET amplification: Preliminary TATTON Phase Ib/IIa data for the savolitinib/Tagrisso® combination regimen were presented at the 2019 AACR Annual Meeting for a total of 43 evaluable patients who were T790M- and had not previously received a third-generation EGFR inhibitor;
  - 31% ORR and 9.7 months' median duration of response in patients with acquired resistance to Tagrisso<sup>®</sup> driven by MET amplification: Preliminary TATTON Phase Ib/IIa data for the savolitinib/Tagrisso<sup>®</sup> combination regimen were also presented at the 2019 AACR Annual Meeting for a total of 39 evaluable patients who had reported disease progression after receiving a third-generation EGFR inhibitor. The SAVANNAH Phase IIb registration intent study, which is being conducted in North

and South America, Europe and Asia in this target patient population, dosed its first patient in early 2019;

• Emerging signal for savolitinib/Imfinzi<sup>®</sup> (PD-L1) combination in renal cell carcinoma ("RCC"): Interim results for the papillary RCC ("PRCC") cohort of the CALYPSO Phase II study were presented at the 2019 American Society of Clinical Oncology Genitourinary Symposium ("ASCO GU") reporting a 27% ORR for all 41 patients and a 32% ORR for the 28 previously untreated patients. The combination was tolerable and associated with durable responses in PRCC.

# Further progress in early/proof-of-concept clinical trials and discovery, including:

- HMPL-523 potential first-in-class selective Syk inhibitor: A Phase Ib dose expansion study in both China and Australia accelerated enrollment in H1 2019 in multiple sub-types of non-Hodgkin's lymphoma ("NHL"). We intend to use Phase Ib data to guide registration strategy in China during late 2019; and multiple U.S. / Europe sites are also now open for a Phase I/Ib study with patient screening underway.
- HMPL-689 potential best-in-class selective PI3Kδ inhibitor: A recommended dose for Phase II study has been selected based on the China Phase I study; U.S. / Europe IND applications cleared; and
- **IND submission in China for HMPL-306:** A novel selective small molecule TKI of isocitrate dehydrogenase ("IDH") 1/2, discovered in-house with IND submitted H1 2019.

### Major organizational expansion, including:

- **Expansion of international clinical and regulatory operations:** accelerated expansion of New Jersey team to support development of multiple un-partnered compounds outside of Asia; and
- **Establishment of China oncology commercial organization:** currently numbering about 60 commercial staff, primarily focused on medical affairs and preparation for potential surufatinib launch in late 2020.

# POTENTIAL UPCOMING KEY EVENTS

China – H2 2019	Global – H2 2019
<ol> <li>Savolitinib – Registration study completion – MET Exon 14 deletion NSCLC (occurred July);</li> </ol>	<ol> <li>HMPL-523 (Syk) – Phase I – Initiate U.S. / E.U. Phase I/Ib in indolent NHL;</li> </ol>
<ol> <li>Surufatinib – Phase III data (SANET-ep) – presentation at scientific conference;</li> </ol>	<ol> <li>HMPL-689 (PI3Kō) – Phase I – Initiate U.S. / E.U. Phase I/Ib in indolent NHL;</li> </ol>
<ol> <li>Surufatinib – NDA submission – in non- pancreatic NET;</li> </ol>	3. Savolitinib – Phase II data (VIKTORY) – gastric cancer data (patient tumor molecular profiling).
<ol> <li>Fruquintinib – Phase III data (FALUCA) – submit for presentation in NSCLC at conference;</li> </ol>	
5. <b>Fruquintinib</b> – <b>Reimbursement</b> – possible Elunate <sup>®</sup> inclusion in China NRDL in Q4 2019.	
China – H1 2020	Global – H1 2020
China – H1 2020 6. Fruquintinib – Phase III interim analysis (FRUTIGA) – 2 <sup>nd</sup> interim in gastric cancer;	Global – H1 2020 4. Surufatinib – Phase II/III start – initiate U.S. / E.U. study in pancreatic NET;
6. Fruquintinib – Phase III interim analysis	4. Surufatinib – Phase II/III start – initiate U.S. /
<ul> <li>6. Fruquintinib – Phase III interim analysis (FRUTIGA) – 2<sup>nd</sup> interim in gastric cancer;</li> <li>7. Surufatinib – Phase III interim analysis</li> </ul>	<ul> <li>4. Surufatinib – Phase II/III start – initiate U.S. / E.U. study in pancreatic NET;</li> <li>5. Fruquintinib – Phase II/III start – initiate U.S. /</li> </ul>
<ol> <li>Fruquintinib – Phase III interim analysis (FRUTIGA) – 2<sup>nd</sup> interim in gastric cancer;</li> <li>Surufatinib – Phase III interim analysis (SANET-p) – planned final interim analysis;</li> <li>Savolitinib – NDA submission – in MET Exon</li> </ol>	<ol> <li>Surufatinib – Phase II/III start – initiate U.S. / E.U. study in pancreatic NET;</li> <li>Fruquintinib – Phase II/III start – initiate U.S. / E.U. Phase II/III study in metastatic CRC;</li> <li>Savolitinib – Phase II data (CALYPSO) –</li> </ol>

# FINANCIAL GUIDANCE

We are providing the following updated Financial Guidance for the year ending December 31, 2019. Our updated guidance takes into account the weakening of the RMB, which was down 6% against the U.S. dollar during H1 2019 (using the average exchange rate for the period) relative to the same period last year due to global macroeconomic factors. We expect this trend to continue through the balance of 2019, and this depreciation of the RMB has the effect of reducing our R&D expenses in China in U.S. dollar terms.

In addition, we have both expanded and extended existing studies of surufatinib and fruquintinib in the U.S. ahead of upcoming regulatory authority end of Phase II meetings. This will move certain start-up costs of our global Phase II/III registration studies on surufatinib and fruquintinib into 2020.

	2019 Previous Guidance	2019 Current Guidance	Adjustments
Adjusted R&D Expenses	\$(160) – (200) million	\$(130) – (170) million	\$(30) million
Adjusted Group Net Cash Flows excluding financing activities	\$(120) – (150) million	\$(90) – (120) million	\$(30) million

**Use of Non-GAAP Financial Measures** – References in this announcement to adjusted R&D expenses, adjusted Group net cash flows and adjusted Group net cash flows excluding financing activities and financial measures reported at CER are based on non-GAAP financial measures. Please see the "Use of Non-GAAP Financial Measures and Reconciliation" below for further information relevant to the interpretation of these financial measures to the most comparable GAAP measures.

#### About Chi-Med

Chi-Med (AIM/Nasdaq: HCM) is an innovative biopharmaceutical company which researches, develops, manufactures and markets pharmaceutical products. Its Innovation Platform, Hutchison MediPharma, has about 440 scientists and staff focusing on discovering, developing and commercializing targeted therapeutics and immunotherapies in oncology and autoimmune diseases. It has a portfolio of eight cancer drug candidates currently in clinical studies around the world. Chi-Med's Commercial Platform manufactures, markets, and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China.

Chi-Med is headquartered in Hong Kong and is dual-listed on the AIM market of the London Stock Exchange and the Nasdaq Global Select Market. For more information, please visit: <u>www.chi-med.com</u>.

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### References

Unless the context requires otherwise, references in this announcement to the "Group," the "Company," "Chi-Med," "Chi-Med Group," "we," "us," and "our," mean Hutchison China MediTech Limited and its consolidated subsidiaries and joint ventures unless otherwise stated or indicated by context.

### Past Performance and Forward-Looking Statements

The performance and results of operations of the Group contained within this announcement are historical in nature, and past performance is no guarantee of future results of the Group. This announcement contains forward-looking statements within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by words like "will," "expects." "anticipates," "future," "intends," "plans," "believes," "estimates," "pipeline," "could," "potential," "believe," "first-in-class," "best-in-class," "designed to," "objective," "guidance," "pursue," or similar terms, or by express or implied discussions regarding potential drug candidates, potential indications for drug candidates, a potential SEHK listing and concurrent global offering of our securities or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that any of our drug candidates will be approved for sale in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such drug candidates will achieve any particular revenue or net income levels. In particular, management's expectations could be affected by, among other things: unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including the inability to meet our key study assumptions regarding enrollment rates, timing and availability of subjects meeting a study's inclusion and exclusion criteria and funding requirements, changes to clinical protocols, unexpected adverse events or safety, quality or manufacturing issues; the inability of a drug candidate to meet the primary or secondary endpoint of a study; the inability of a drug candidate to obtain regulatory approval in different jurisdictions or gain commercial acceptance after obtaining regulatory approval; global trends toward health care cost containment, including ongoing pricing pressures; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes, and government investigations generally; and general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries and uncertainties regarding future global exchange rates. For further discussion of these and other risks, see Chi-Med's filings with the U.S. Securities and Exchange Commission and on AIM. Chi-Med is providing the information in this announcement as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

In addition, this announcement contains statistical data and estimates that Chi-Med obtained from industry publications and reports generated by third-party market research firms. Although Chi-Med believes that the publications, reports and surveys are reliable, Chi-Med has not independently verified the data and cannot guarantee the accuracy or completeness of such data. You are cautioned not to give undue weight to this data. Such data involves risks and uncertainties and are subject to change based on various factors, including those discussed above.

# **Inside Information**

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.



# FINANCIAL REVIEW

Chi-Med Group revenue for the six months ended June 30, 2019 was \$102.2 million (H1-18: \$102.2m). Revenue from the Commercial Platform increased to \$90.2 million (H1-18: \$88.6m) driven mainly by continued progress on our Hutchison Sinopharm business. Revenue from the Innovation Platform decreased to \$12.0 million in the first half of 2019 (H1-18: \$13.6m), reflecting a transitioning from a focus on earning service fees from our partners through development collaborations to reporting product sales revenue and royalty income from the commercial launch of our innovations such as Elunate<sup>®</sup>.

It should be noted that Group revenues do not include the revenues of our two large-scale, 50/50 joint ventures in China, Shanghai Hutchison Pharmaceuticals Limited ("SHPL") and Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited ("HBYS"), since these are accounted for using the equity method.

In the first half of 2019, our Commercial Platform, which is a material source of profit and cash for Chi-Med, recorded an operating profit of \$30.8 million (H1-18: \$31.0m). This reflected growth in SHPL's coronary artery disease business offset by the halt of service fees from Seroquel<sup>®</sup> and weakening of the RMB against the U.S. dollar. The Innovation Platform incurred an operating loss of \$63.9 million (H1-18: operating loss of \$53.1m) as a result of progress on virtually all aspects of our R&D operations in support of our pipeline of eight novel drug candidates.

Net corporate unallocated expenses, primarily Chi-Med Group overhead and operating costs, increased to \$7.3 million (H1-18: \$4.9m) mainly due to organizational expansion and increased professional fees associated with preparations for our potential listing on The Stock Exchange of Hong Kong Limited ("SEHK").

Consequently, Chi-Med Group's operating loss was \$40.3 million (H1-18: operating loss of \$27.0m).

The aggregate of interest and income tax expenses of Chi-Med Group, as well as net income attributable to non-controlling interests was \$5.0 million (H1-18: \$5.7m).

The resulting total Group net loss attributable to Chi-Med was \$45.4 million (H1-18: net loss of \$32.7m).

As a result, Group net loss attributable to Chi-Med in the first half of 2019 was \$0.07 per ordinary share / \$0.34 per American depositary share ("ADS"), compared to net loss attributable to Chi-Med of \$0.05 per ordinary share / \$0.25 per ADS, in H1 2018.

# **Cash and Financing**

We have used, and will continue to use, financial discipline in aiming to partially offset increasing clinical investment with cash generated in our operating activities. This includes cash from dividends paid by our non-consolidated Commercial Platform joint ventures, collaboration payments received from our multinational pharmaceutical company partners, and now increasingly net income, manufacturing and royalty revenues from our launched products. These cash inflows offset a material portion of our R&D expenses, and as a result, total Chi-Med Group net cash flows, excluding financing activities, during the first half of 2019 was -\$34.2 million despite R&D expenses of \$74.5 million, both on an as adjusted (non-GAAP) basis.

As of June 30, 2019, we had available cash resources of \$383.6 million (December 31, 2018: \$420.3m) at the Chi-Med Group level. This included cash and cash equivalents and short-term investments of \$237.3 million (December 31, 2018: \$301.0m) and unutilized bank borrowing facilities of \$146.3 million (December 31, 2018: \$119.3m). In addition, as of June 30, 2019, our non-consolidated joint ventures (SHPL, HBYS and Nutrition Science Partners Limited) held \$64.0 million (December 31, 2018: \$59.2m) in available cash resources.

Outstanding bank loans, at the Chi-Med Group level, as of June 30, 2019 amounted to nil (December 31, 2018: \$26.7m). Also, as of June 30, 2019, our non-consolidated joint ventures had no outstanding bank loans.

# Equity Capital Markets ("ECM") update

In mid-April 2019, Chi-Med announced our proposed intention to list our shares on the SEHK. We continue to consider this however, our listing application and potential concurrent global offering remain subject to, among other things, market conditions.



In July 2019, our largest shareholder CK Hutchison<sup>1</sup> completed most of its previously announced plan to reduce its shareholding in Chi-Med to below 50% by reducing its shareholding from 60.2% to 51.2%. Upon the shareholding of CK Hutchison in Chi-Med falling below 50%, Chi-Med will no longer be a consolidated subsidiary of CK Hutchison thereby reducing the impact on CK Hutchison's earnings of Chi-Med's investment in the accelerated development of its global pipeline. Going forward CK Hutchison is expected to remain Chi-Med's largest shareholder for the foreseeable future and Chi-Med will continue to benefit from the long term support of its founding shareholder.

We believe that our current cash resources including short-term investments, along with our cash flow from operations, dividend payments and potential bank borrowings, are sufficient for Chi-Med to reach multiple value inflection points on our pipeline. We also have the added potential to access non-dilutive finance that could be derived from the disposal of certain non-core Commercial Platform assets.

This provides us with considerable flexibility on the type, and timing, of any future ECM activities.

<sup>[1]</sup> CK Hutchison Holdings Limited ("CK Hutchison") (SEHK: 1), a multinational conglomerate with revenues of \$58 billion in 2018 and employing over 300,000 people in over 50 countries across the world.



# **OPERATIONS REVIEW**

# INNOVATION PLATFORM

Chi-Med's pipeline of novel drug candidates has been created and developed by our Innovation Platform, an in-house R&D operation which was started in 2002. Since then, we have built a large team of about 440 scientists and staff (December 31, 2018: ~420) based mainly in China. We operate a fully-integrated drug discovery and development operation covering chemistry, biology, pharmacology, toxicology, chemistry and manufacturing controls for clinical and commercial supply, clinical and regulatory and other functions. Looking ahead, we plan to further expand and leverage this platform to produce and commercialize a stream of novel drug candidates with global potential that can improve the treatment of patients with cancer and autoimmune diseases globally.

Innovation Platform revenue in H1 2019 was \$12.0 million (H1-18: \$13.6m) mainly from service fee payments from AstraZeneca and Lilly in addition to initial product revenue and royalties from Elunate<sup>®</sup>. We are gradually transitioning the revenue model of our Innovation Platform from a fee for service model, in which Chi-Med provided multi-national partners services associated with research and clinical development, to one focused on generating revenues from product sales and royalty income from our innovative drugs.

Net loss attributable to Chi-Med increased to \$63.8 million (H1-18: net loss of \$52.9m) as a result of increased R&D expenses of \$74.5 million (H1-18: \$66.7m) on an as adjusted (non-GAAP) basis driven by progress on virtually all aspects of our R&D operations in support of our pipeline of eight drug candidates.

Since inception, the Innovation Platform has dosed over 4,800 patients/subjects, with over 400 in H1 2019, in clinical trials of our drug candidates in over 30 active or completed studies.

### **Product Pipeline Progress**

#### SAVOLITINIB (AZD6094)

Savolitinib is a potent and selective inhibitor of MET, an enzyme which has been shown to function abnormally in many types of solid tumors. In clinical studies to date in over 1,000 patients globally, savolitinib has shown promising signs of clinical efficacy in patients with MET gene alterations in lung cancer, kidney cancer, and gastric cancer with an acceptable safety profile.

We are currently testing savolitinib in global partnership with AstraZeneca, both as a monotherapy and in combinations. Two ongoing studies, which subject to positive clinical outcome, are designed to support NDA submission in lung cancer. Several additional studies, mostly proof-of-concept, have reported or will report in 2019 and subject to outcomes could warrant further development.

**Savolitinib – Lung cancer:** MET is an increasingly important target in NSCLC. The table below shows a summary of the clinical studies for savolitinib in lung cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib monotherapy	MET Exon 14 deletion	China	II Registration	Target enrollment completed	NCT02897479
Savolitinib and Tagrisso <sup>®</sup>	TATTON: 2L/3L EGFRm+; EGFR TKI refractory; MET+	Global	Ib/II	Completed enrollment; preliminary data presented at AACR 2019	NCT02143466
Savolitinib and Tagrisso®	SAVANNAH: 2L/3L EGFRm+; Tagrisso <sup>®</sup> refractory; MET+	Global	II (potential registration)	Initiated in Dec 2018	NCT03778229
Savolitinib and Iressa®	2L EGFRm; Iressa® ref; MET+	China	Ib/II	Completed	NCT02374645

<u>MET Exon 14 deletion NSCLC (NCT02897479)</u> – It is estimated that 2-3% of NSCLC patients have MET Exon 14 deletion, which is believed to play an important role in driving tumor growth.

Recent data from the 2019 ASCO Meeting showed that two selective MET inhibitors in development outside of China, capmatinib and tepotinib, had an overall ORR ranging from 41% to 68% in clinical studies in MET Exon 14 deletion NSCLC patients. Xalkori<sup>®</sup>, a multi-kinase inhibitor with MET inhibitory activity, demonstrated a lower ORR of approximately 32% in clinical studies.

We are conducting a Phase II registration intent study of savolitinib as a monotherapy for MET Exon 14 deletion NSCLC patients who have progressed following prior systemic therapy, or unable to receive chemotherapy. During 2019 AACR, interim data were presented on 41 treated patients, of which only 31 patients were efficacy



evaluable. The overall data was encouraging, with efficacy in-line with other selective MET inhibitors, supporting the continuation of the study as originally planned. Treatment emergent CTC grade  $\geq$ 3 adverse events with greater than 5% incidence related to savolitinib treatment were increased aspartate aminotransferase (7%) and increased alanine aminotransferase (7%). We have now reached our enrollment goal for this Phase II registration study, and subject to clinical outcome later this year, this indication has high potential to be savolitinib's first NDA in H1 2020.

<u>Tagrisso<sup>®</sup> (osimertinib) resistance in NSCLC:</u> Since its U.S. Food and Drug Administration (FDA) approval in November 2015, Tagrisso<sup>®</sup> has been established as an important treatment for EGFR mutation positive NSCLC and has now been approved in over 80 countries. Tagrisso<sup>®</sup> global sales were \$1.9 billion in 2018, its third year since launch, and \$1.4 billion in the first half of 2019 making it AstraZeneca's highest selling medicine.

Given the significant use of Tagrisso<sup>®</sup> for EGFR mutation positive NSCLC, understanding the mechanism of acquired resistance, following Tagrisso<sup>®</sup> treatment, is a key clinical question to inform the next treatment choice.

At the European Society of Medical Oncology Congress in 2018, AstraZeneca presented data on the acquired resistance spectrum detected in circulating tumor cells in patient plasma after progression on Tagrisso<sup>®</sup> when used in the first-line (FLAURA) and second-line T790M (AURA3) Phase III studies. MET amplification was the most frequent mechanism of acquired resistance to Tagrisso<sup>®</sup>, with 15% of patients in the FLAURA study, and 19% of patients in AURA3 study exhibiting MET amplification after treatment with Tagrisso<sup>®</sup>.

<u>TATTON study (Part B) and TATTON study (Part D); Phase Ib/II expansion studies of savolitinib in combination</u> <u>with Tagrisso® in NSCLC EGFR mutation positive TKI refractory patients (NCT02143466)</u> – In 2016, we initiated a global Phase Ib/II expansion study in NSCLC, the TATTON (Part B) study, aiming to recruit sufficient MET gene amplified patients who had progressed after prior treatment with EGFR inhibitors to support a decision on global Phase II/III registration strategy.

# *First-generation EGFR TKI, such as Iressa® and Tarceva®, refractory patients with acquired resistance driven by MET amplification*

In March 2019, preliminary TATTON (Part B) data were presented at AACR 2019 aimed at expanding and corroborating preliminary data presented at the World Conference on Lung Cancer ("WCLC") in 2017. The AACR 2019 presentation also included median duration of response data for the first time, since it was not mature at the time of WCLC 2017. Data for the savolitinib in combination with Tagrisso<sup>®</sup> was presented for a total of 43 evaluable patients (46 total patients) who were T790M- and who had not previously received a third-generation EGFR inhibitor. There were 24 confirmed responses (56% of efficacy evaluable patients), four unconfirmed responses, 12 other patients with stable disease, for a total of 40 patients who experienced disease control (93% of efficacy evaluable patients). The median duration of response was 7.1 months, with an interquartile range from 4.1 months to 10.7 months. CTC grade  $\geq$ 3 adverse events with greater than 5% incidence independent of causality were increased aspartate aminotransferase (8%), increased neutrophil count (8%), fatigue (7%) and pain (7%).

In late 2017, the TATTON study (Part D) was initiated to study Tagrisso<sup>®</sup> combined with a lower savolitinib dose (300 mg once daily) in the context of maximizing long-term tolerability of the combination. Enrollment has now been completed, patients continue to be treated and clinical data continues to mature.

# Tagrisso<sup>®</sup> or another experimental third-generation EGFR TKI refractory patients with acquired resistance driven by MET amplification

Also in March 2019 at AACR, further TATTON (Part B) preliminary data, for the savolitinib in combination with Tagrisso<sup>®</sup>, were presented for a total of 39 evaluable patients, that had progressed on Tagrisso<sup>®</sup> monotherapy and harbored MET amplification. There were 12 confirmed responses (31% of evaluable patients), five unconfirmed responses and 16 patients with stable disease, totaling 33 patients who experienced disease control (85% of efficacy evaluable patients). The median duration of response was 9.7 months, with an interquartile range from 5.5 months to an incalculable higher figure at the time of data cut-off. Overall the combination regimen of savolitinib and Tagrisso<sup>®</sup> was tolerable with the only CTC grade  $\geq$ 3 adverse event with greater than 5% incidence independent of causality was decreased appetite (6%).

SAVANNAH (NCT03778229) – Based on the encouraging results of the multiple TATTON studies, AstraZeneca has initiated a global Phase II study of savolitinib / Tagrisso® combination in EGFR mutation positive NSCLC patients who have progressed following first or second-line Tagrisso® therapy due to MET amplification – The SAVANNAH study is a single-arm study, in North and South America, Europe and Asia, targeting an interim analysis and regulatory agency discussion in mid-2020 which will guide registration strategy for this indication.

<u>Savolitinib / Iressa<sup>®</sup> combination (NCT02374645)</u> – Separately, a Phase Ib study combining AstraZeneca's first-generation EGFR TKI Iressa<sup>®</sup> with savolitinib has been completed in China. Chi-Med and AstraZeneca are evaluating this opportunity in the context of the evolving treatment paradigm for EGFRm NSCLC.

**Savolitinib – Kidney cancer:** The table below shows a summary of the clinical studies for savolitinib in kidney cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib and Imfinzi®	CALYPSO: Papillary RCC	UK/Spain	II	Interim - Presented at ASCO GU 2019	NCT02819596
Savolitinib and Imfinzi®	CALYPSO: Clear cell RCC; VEGFR TKI refractory	UK/Spain	II	Enrolling - Data late 2019/early 2020	NCT02819596

<u>Savolitinib and Immunotherapy Combinations</u> – Immunotherapy combinations are rapidly changing the treatment landscape in kidney cancer. Anti-PD-L1 antibodies have been associated with clinical benefits in metastatic RCC, and MET dysregulation has been considered to play an important role in the pathogenesis of RCC. Moreover, it is believed that the MET signaling pathway may have a complex interplay with the immune system through recruitment of immune suppressive cells such as neutrophils.

<u>CALYPSO Phase II in RCC of savolitinib with Imfinzi® PD-L1 inhibitor combination (NCT02819596)</u> – The CALYPSO study is an investigator initiated open-label Phase I/II study of savolitinib in combination with Imfinzi®, an anti-PD-L1 antibody owned by AstraZeneca. The study is evaluating treatment of PRCC and clear cell RCC patients at sites in the U.K. and Spain.

*PRCC cohort* – Interim data for the PRCC cohort of the CALYPSO Phase II study were presented at 2019 ASCO GU showing encouraging efficacy across all PRCC patients (with or without MET amplification). The interim CALYPSO data, reported ORR of 27% (11/41), while median PFS was 5.3 months (95% CI: 1.5-12.0 months). Median OS was immature/not reached. For previously untreated patients (n=28), ORR was 32% (9/28). The combination was tolerable with edema (10%), nausea (5%), and transaminitis (5%) being most frequent treatment related Grade ≥3 adverse events. The investigators concluded that the Imfinzi<sup>®</sup> / savolitinib combination is associated with encouraging clinical efficacy and durable responses in PRCC. The CALYPSO study continues, with further data expected to be presented at an upcoming scientific conference in 2020.

**Savolitinib – Gastric cancer:** Multiple Phase II studies have been conducted in Asia to study savolitinib in MET-driven gastric cancer patients. A total of well over 1,000 gastric cancer patients had been screened in these studies and those patients with confirmed MET-driven disease were treated. The table below shows a summary of our clinical trials for savolitinib in gastric cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib monotherapy	Gastric cancer (MET amplification) and VIKTORY (in South Korea)	China & South Korea	Ib/II	Completed in China; VIKTORY complete; to publish 2019	NCT01985555 / NCT02449551
Savolitinib and Taxotere <sup>®</sup>	VIKTORY: Gastric cancer (MET amplification)	South Korea	II	Enrollment stopped (Patients directed to	NCT02447406
Savolitinib and Taxotere <sup>®</sup>	VIKTORY: Gastric cancer (MET over-expression)	South Korea	II	savolitinib mono due to high efficacy observed)	NCT02447380

<u>Savolitinib monotherapy in MET amplified gastric cancer patients (NCT01985555 / NCT02449551)</u> – Preliminary results were presented at the Chinese Society of Clinical Oncology conference in late 2017 for the efficacy evaluable MET gene amplified patients in China. This China study concluded that savolitinib monotherapy demonstrated promising anti-tumor efficacy in gastric cancer patients with MET gene amplification, and the potential benefit to these patients clearly warranted further exploration.

The South Korean study, known as VIKTORY, and is an umbrella study with MET amplification as one of its cohorts, is run and sponsored by the Samsung Medical Center in South Korea. The VIKTORY Phase II study is now complete and the full data set is expected to be published in a scientific journal in 2019.

**Savolitinib – Prostate cancer:** The table below shows a summary of the clinical study for savolitinib in prostate cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib monotherapy	Metastatic Castration-Resistant Prostate Cancer	Canada	II	Enrolling	NCT03385655

This study is an umbrella study and is sponsored by the Canadian Cancer Trials Group. The study targets to enroll approximately 500 patients with savolitinib being one of four cohorts.

# FRUQUINTINIB (ELUNATE®)

Fruquintinib is a highly selective and potent oral inhibitor of VEGFR 1/2/3 that was designed to be a global bestin-class VEGFR inhibitor for many types of solid tumors. VEGFR inhibitors play a pivotal role in tumor-related angiogenesis, cutting off the blood supply that a tumor needs to grow rapidly.

Fruquintinib was designed to improve kinase selectivity in comparison to other approved small molecule TKIs, to minimize off-target toxicities, improve tolerability and provide more consistent target coverage. The high tolerability in patients to date, along with fruquintinib's low potential for drug-drug interaction based on preclinical assessment, suggests that it may be highly suitable for combinations with other anti-cancer therapies.

The global market for anti-angiogenesis therapies was estimated at over \$16 billion in 2018, including both monoclonal antibodies and small molecules approved in around 30 tumor settings.

Chi-Med retains all rights to fruquintinib outside of China and is partnered with Lilly in China.

The table below shows a summary of the clinical studies for fruquintinib.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Fruquintinib monotherapy	FRESCO: ≥3L CRC; chemotherapy refractory	China	III	Approved and launched	NCT02314819
Fruquintinib monotherapy	3L/4L CRC; Stivarga <sup>®</sup> /Lonsurf <sup>®</sup> ref./intol.	US/EU	Ib	US/EU Ph.II/III registration study in planning	NCT03251378
Fruquintinib and paclitaxel	FRUTIGA: 2L gastric cancer	China	III	Enrolling; Interim analysis conducted in early 2019	NCT03223376
Fruquintinib monotherapy	FALUCA: 3L NSCLC; chemotherapy refractory	China	III	Completed. Failed to meet primary endpoint	NCT02691299
Fruquintinib and Iressa®	1L NSCLC; EGFRm	China	II	Enrollment completed	NCT02976116
Fruquintinib and genolimzumab (PD-1)	2L metastatic CRC/NSCLC	China	Ib	Enrolling	NCT03977090
Fruquintinib and Tyvyt <sup>®</sup> (PD-1)	Solid tumors	China	Ib/II	Enrolling	NCT03903705
Fruquintinib and Tyvyt <sup>®</sup> (PD-1)	Solid tumors	US	Ι	In planning	TBD

#### Fruquintinib – Colorectal Cancer:

Fruquintinib capsules, sold under the brand name Elunate<sup>®</sup>, were approved for marketing in China by the National Medical Products Administration ("NMPA") in September 2018 and commercially launched by Lilly in late November 2018. Elunate<sup>®</sup> is for the treatment of patients with metastatic CRC that have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan, including those who have previously received anti-VEGF therapy and/or anti-EGFR therapy (RAS wild type).

#### Elunate<sup>®</sup> launch update:

*Pricing* – Elunate<sup>®</sup> was launched with an initial retail price of RMB21,960 (\$3,260) per cycle, on a four-week per cycle basis paid for out-of-pocket by patients in China. To broaden access to Elunate<sup>®</sup>, Lilly has implemented a means-based patient access program, whereby patients pay for three 28-day cycles of Elunate<sup>®</sup> (cycles one, two and five) at the full price. Outside of these three paid-for cycles, Elunate<sup>®</sup> is provided for at no cost.

*Reimbursement* – During the first half of 2019 both Lilly and Chi-Med have been actively working to expand government reimbursement of Elunate<sup>®</sup> in China. In early 2019 Elunate was included in the reimbursement list for Zhuhai, a city of 1.6 million people, and in June 2019 it was included into the Shanghai provincial reimbursement drug list covering 15.0 million patients.

More importantly, we are now focused on potentially trying to secure inclusion in the next update of the NRDL which is expected to be finalized in early Q4 2019. Inclusion in the NRDL would trigger distribution of Elunate<sup>®</sup> in all state-run hospital pharmacies in China and open up reimbursement for the over 317 million people included in the main medical insurance program for urban employees in China.

*In-market Sales performance* – Sales of Elunate<sup>®</sup>, as provided by Lilly, totaled \$11.4 million (RMB77.1 million) in the first half of 2019 (H1-2018: nil) resulted primarily from out-of-pocket payments from patients with support via the means-tested patient access program.

This represents first six-month revenue for Elunate<sup>®</sup> that is well ahead, at the same stage, of the five small molecule VEGFR inhibitors previously launched by multinational companies in China. These products, all

reported on a CER basis, include: Nexavar<sup>®</sup> (sorafenib, Bayer AG) launched in 2006 with 2007 sales of \$18.6 million (RMB125.1m); Sutent<sup>®</sup> (sunitinib, Pfizer, Inc.), launched in 2007 with 2008 sales of \$7.4 million (RMB49.9m); Inlyta<sup>®</sup> (axitinib, Pfizer, Inc.), launched in 2015 with 2016 sales of \$12.1 million (RMB81.6m); Votrient<sup>®</sup> (pazopanib, Novartis International AG), launched in 2017 with 2018 sales of \$12.5 million (RMB84.0m); and Stivarga<sup>®</sup> (regorafenib, Bayer AG), launched in 2017 with first six-month sales of \$4.7 million (RMB32.0m) and 2018 sales of \$21.2 million (RMB142.7m).

*Chi-Med Revenues in H1 2019 from Elunate*<sup>®</sup> – Chi-Med receives four types of revenue from Lilly associated with Elunate<sup>®</sup>: (1) manufacturing product sales; (2) royalties; (3) fees for development-related services; and (4) reimbursement of development costs of certain initial indications. With the commercial launch of Elunate<sup>®</sup> we are transitioning to a model in which our main revenues from Lilly will be manufacturing product sales and royalties. During the first half of 2019, Chi-Med reported revenues from Lilly totaling \$6.1 million (H1-18: \$6.0m) including manufacturing product sales of \$3.0 million (H1-18: nil); royalties of \$1.7 million (H1-18: nil); service fees of \$0.8 million (H1-18: \$1.1m); and clinical trial cost reimbursement of \$0.6 million (H1-18: \$4.9m).

*Outlook for Elunate® in colorectal cancer (CRC)* – Elunate®'s main competitor in third-line CRC in China is Stivarga® (regorafenib), a first generation small molecule multi-kinase inhibitor, from Bayer AG. Stivarga® in-market sales in China, which were \$21.2 million in the whole of 2018, increased rapidly to \$19.7 million (RMB133m) in Q1 2019. Growth was likely as a result of its inclusion in the NRDL in October 2018, and entry into hospital pharmacies, as well as its approval in second-line hepatocellular carcinoma in March 2018.

The efficacy and safety-profile advantages for Elunate<sup>®</sup> over Stivarga<sup>®</sup> in third-line CRC are well documented, with Stivarga<sup>®</sup> carrying a black-box safety warning for liver toxicity in the United States. In the FRESCO study, Elunate<sup>®</sup> demonstrated a tolerable liver safety profile which could be very important for advanced CRC patients, particularly the high proportion of those with liver metastases. Furthermore, patients in the FRESCO study who had prior exposure to anti-VEGF therapies derived robust benefit from Elunate<sup>®</sup> treatment, a clear point of differentiation as compared to Stivarga<sup>®</sup>.

<u>Global development of fruquintinib in CRC</u> – We are currently enrolling a Phase Ib study in the U.S. and have begun planning for a Phase II/III registration study in the United States and Europe in third or fourth-line metastatic CRC patients who are resistant to or intolerant of prior treatment with Stivarga<sup>®</sup> or Lonsurf<sup>®</sup> (a cytotoxic chemotherapy agent approved in third-line CRC in various countries excluding China). We expect to begin this study in 2020.

# Fruquintinib – Gastric Cancer:

<u>Phase III study of fruquintinib in combination with paclitaxel in gastric cancer (second-line) (NCT03223376)</u> – In October 2017, we initiated the FRUTIGA study, a randomized, double-blind, Phase III study in China to evaluate the efficacy and safety of fruquintinib combined with paclitaxel compared with paclitaxel monotherapy for second-line treatment of advanced gastric cancer. Over 500 patients are expected to be enrolled into the FRUTIGA study at a 1:1 ratio with the primary endpoint of this study being OS. Enrollment is expected to be completed in mid-2020 with top line results in early 2021.

In April 2019, we conducted an interim analysis of the FRUTIGA study for futility. The analysis evaluated PFS and OS trends after six months of therapy for the first 100 patients recruited into the study. The IDMC recommended to continue the study without changes.

# Fruquintinib – NSCLC:

<u>Phase III study of fruquintinib monotherapy in third-line NSCLC (NCT02691299)</u> – In November 2018, we announced the outcome of FALUCA, the Phase III trial of fruquintinib in advanced NSCLC patients in China who have failed two lines of systemic chemotherapy. The trial did not meet the primary endpoint to demonstrate a statistically significant increase in OS compared to placebo. However, fruquintinib demonstrated a statistically significant increase in OS compared to placebo. However, fuquintinib demonstrated a statistically significant increase as compared to the placebo. The safety profile of the trial was in line with that observed in prior clinical studies. We intend to present a detailed analysis of the study in September at WCLC 2019 in Barcelona, Spain.

<u>Phase II study of fruquintinib in combination with Iressa® in first-line NSCLC (NCT02976116)</u> – In early 2017, we initiated a multi-center, single-arm, open-label, dose-finding Phase II study of fruquintinib in combination with Iressa® in China in the first-line setting for patients with advanced or metastatic NSCLC with EGFR activating mutations. We have enrolled about 50 patients in this study with the objective of evaluating the safety and tolerability as well as the efficacy of the combination therapy.

Preliminary interim data for this study were presented in late 2017 at WCLC, showing an encouraging response and safety profile. Fruquintinib's safety and tolerability profile, resulting from its high kinase selectivity, combined with better flexibility to manage treatment emergent toxicities due to its shorter half-life than monoclonal antibody anti-angiogenesis therapies, makes it a suitable combination partner for EGFR TKIs. The primary objective of this exploratory study is to determine the safety and tolerability and median PFS of the fruquintinib and Iressa<sup>®</sup> combination. The study is now complete and we expect to submit data for presentation at an upcoming scientific conference.

# Fruquintinib – Combinations with Checkpoint Inhibitors:

In November 2018, we entered into two collaboration agreements to evaluate the safety, tolerability and efficacy of fruquintinib in combination with checkpoint inhibitors. These include a global collaboration with Innovent to evaluate the combination of fruquintinib with Innovent's Tyvyt<sup>®</sup> (sintilimab, IBI308), a PD-1 monoclonal antibody approved in China in late 2018 and a China collaboration with Genor to evaluate the fruquintinib combination with genolimzumab (GB226), a PD-1 monoclonal antibody being developed by Genor. Phase I studies have now been initiated to establish the safe and effective dose regimens for the fruquintinib combinations with either Tyvyt<sup>®</sup> or genolimzumab, respectively.

# SURUFATINIB (HMPL-012 OR SULFATINIB)

Surufatinib is an oral small molecule angio-immuno kinase inhibitor targeting VEGFR 1, 2 and 3, FGFR1 and CSF-1R kinases that may simultaneously block tumor angiogenesis and immune evasion. Its angio-immuno kinase profile seems to support surufatinib as an attractive candidate for exploration of possible combinations with checkpoint inhibitors against various cancers.

Chi-Med currently retains all rights to surufatinib worldwide.

Surufatinib, as a monotherapy, is in proof-of-concept clinical trials in the U.S. and late-stage clinical trials in China. A summary of these clinical studies is shown in the table below.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Surufatinib monotherapy	SANET-ep: Non-pancreatic NET	China	III	Met primary endpoint; preparing NDA	NCT02588170
Surufatinib monotherapy	SANET-p: Pancreatic NET	China	III	Interim analysis early 2020	NCT02589821
Surufatinib monotherapy	2L Pancreatic NET;	US/EU	Ib	US/EU Ph.II/III registration	NCT02549937
	Sutent <sup>®</sup> /Afinitor <sup>®</sup> refractory			study in planning	
Surufatinib monotherapy	Chemotherapy refractory BTC	China	II/III	Enrolling	NCT03873532
Surufatinib and Tuoyi <sup>®</sup> (PD-1)	Solid tumors	US	I	In planning	TBD
Surufatinib and Tuoyi <sup>®</sup> (PD-1)	Solid tumors	China	I	Enrolling	NCT03879057

# Surufatinib – Neuroendocrine Tumors (NET):

NETs begin in the specialized cells of the body's neuroendocrine system. Cells have traits of both hormoneproducing endocrine cells and nerve cells. NETs are found throughout the body's organ system and have a highly complex and fragmented epidemiology with approximately 55-75% of NETs originating in the gastroentero pancreatic ("GEP") system of the gastrointestinal tract and pancreas, 25-30% originate in the lung or bronchus, and a further 10-20% originate from other or unknown origins.

There were 19,000 newly diagnosed cases of NET in the U.S. in 2018. Importantly, NETs are associated with a relatively long duration of survival compared to other tumors. As a result, there were approximately 141,000 estimated patients living with NETs in the U.S. in 2018. Of this number, up to 90%, or approximately 132,000, were non-pancreatic NET patients.

In China there were approximately 67,600 newly diagnosed NET patients in 2018 and, while no prevalence data exists in China, considering the U.S. incidence to prevalence ratio, there could be as many as 490,000 patients living with the disease. Until such time as NET patients in China are diagnosed earlier and given broader access to treatment options we expect that estimated Prevalence to Incidence ratio in China will likely be lower than that currently observed in the U.S.

NETs can be functional, releasing hormones and peptides that cause symptoms like diarrhea and flushing, or non-functional with no symptoms, but on a high level, NET is classified as either early- or advanced-disease.

Early NETs are generally functional and well-differentiated, looking like healthy cells, growing slowly with a low Mitotic count (mitosis is process by which tumor cells grow and divide) and a low Ki-67 index (Ki-67 is a protein

that increases as cells divide). Treatments for early NETs include somatostatin analogue subcutaneous injections, such as Sandostatin LAR<sup>®</sup> (octreotide) and Somatuline Depot<sup>®</sup> (lanreotide) and Afinitor<sup>®</sup> for welldifferentiated, non-functional gastrointestinal and lung NETs. Somatostatin analogues help alleviate symptoms and slow NET growth, but have limited tumor reduction efficacy and are approved and reimbursed in China. Afinitor<sup>®</sup> is not approved for use in gastrointestinal and lung NETs in China.

Advanced NETs are generally poorly differentiated, looking less like healthy cells, growing more quickly with generally a higher Mitotic count and Ki-67 index. Approved targeted therapies outside China, for patients with advanced NETs include Sutent<sup>®</sup> and Afinitor<sup>®</sup>, both oral treatments, for pancreatic NET and Lutathera<sup>®</sup> (177 Lu-Dotatate), a somatostatin receptor targeting radiotherapy, is approved for somatostatin receptor-positive GEP NETs. Lutathera<sup>®</sup> is a subcutaneous injection, which has a half-life of 72 hours and requires radiopharmaceutical-qualified physicians to administer the drug, making it impractical today for the China market. In China, Sutent<sup>®</sup> and Afinitor<sup>®</sup> are only approved for pancreatic NET and no targeted therapies are approved for the approximately 80% of NET patients with non-pancreatic NET.

<u>Phase III study of surufatinib monotherapy in non-pancreatic NET (SANET-ep) (NCT02588170)</u> – In 2015, we initiated the SANET-ep study, which is a Phase III study in China in patients with low- or intermediate-grade advanced extra-pancreatic NET. In this study, patients are randomized at a 2:1 ratio to receive either an oral dose of 300 mg of surufatinib or placebo once daily on a 28-day treatment cycle. The primary endpoint is PFS, with secondary endpoints including ORR, DCR, duration of response, OS, safety and tolerability.

In June 2019, at the interim analysis of our SANET-ep study, the IDMC confirmed that the trial met its primary endpoint of superiority in PFS as compared to placebo. As a result, the study was un-blinded a year ahead of schedule, and preparations for an NDA submission are now underway for this indication in China.

We believe the benefit of surufatinib as a monotherapy to patients with extra-pancreatic NET in China could be significant as compared to the minimal treatment alternatives currently available to them. We expect to submit the results of this trial for publication or presentation at a scientific conference in late 2019.

<u>Phase III study of surufatinib monotherapy in pancreatic NET (SANET-p) (NCT02589821)</u> – In 2016, we initiated the SANET-p study, which is a Phase III study in China in patients with low- or intermediate-grade, advanced pancreatic NET. In this study, patients are randomized at a 2:1 ratio to receive either an oral dose of 300 mg of surufatinib or a placebo once daily on a 28-day treatment cycle. The primary endpoint is PFS, with secondary endpoints including ORR, DCR, duration of response, OS, safety and tolerability. We expect to conduct a final interim analysis in early 2020.

<u>Global development of surufatinib in NET</u> – Surufatinib is currently in a Phase Ib study in the U.S. in pancreatic NET patients that are refractory to Sutent<sup>®</sup> and Afinitor<sup>®</sup>. Planning is currently underway for a global Phase II/III study that is expected to initiate during H1 2020.

# Surufatinib – Biliary Tract Cancer (BTC):

<u>Phase Ib/IIa study of surufatinib monotherapy in BTC (NCT02966821)</u> – In early 2017, we began a Phase Ib/IIa proof-of-concept study in patients with BTC, a heterogeneous group of rare malignancies arising from the biliary tract epithelia. This is a major unmet medical need for patients who have progressed on first-line chemotherapy, and there is currently no standard of care for these patients.

<u>Phase IIb/III study of surufatinib monotherapy in second line BTC (NCT03873532)</u> – In March 2019, based on our preliminary Phase Ib/IIa data we initiated a registration-intent Phase IIb/III study comparing surufatinib with capecitabine in patients with advanced BTC whose disease progressed on first-line chemotherapy. The study is a randomized, open-label, active-control, multi-center, study investigating the effects of surufatinib versus the chemotherapy agent capecitabine, as a second-line therapy in patients with unresectable or metastatic BTC. The primary endpoint is OS. Secondary outcomes include PFS, ORR, DCR, duration of response, quality of life, tumor biomarkers, and safety.

# Surufatinib – Combinations with Checkpoint Inhibitors:

In November 2018, we entered into collaboration agreements to evaluate the safety, tolerability and efficacy of surufatinib in combination with checkpoint inhibitors. These include a global collaboration to evaluate the combination of surufatinib with Junshi's Tuoyi<sup>®</sup> (toripalimab, JS001), a PD-1 monoclonal antibody approved in China in late 2018. A Phase I safety run-in study of surufatinib in combination with Tuoyi<sup>®</sup> in China is enrolling.

# HMPL-523

HMPL-523 is an oral inhibitor targeting Syk, a key protein involved in B-cell signaling. We currently retain all rights to HMPL-523 worldwide. The table below shows a summary of the clinical studies for HMPL-523.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-523 monotherapy	Indolent non-Hodgkin's lymphoma	Australia	Ib	Enrolling	NCT02503033
HMPL-523 monotherapy	Indolent non-Hodgkin's lymphoma	US/EU	Ι	Enrolling	NCT03779113
HMPL-523 monotherapy	Multiple sub-types of B-cell malignancies	China	I/Ib	Enrolling	NCT02857998
HMPL-523 and Vidaza®	Acute myeloid leukemia	China	Ι	Enrolling	NCT03483948
HMPL-523 monotherapy	Immune thrombocytopenia purpura	China	I/Ib	Enrolling	NCT03951623

<u>Phase Ib studies of HMPL-523 in indolent non-Hodgkin's lymphoma and multiple subtypes of B cell</u> <u>malignancies (NCT02503033/NCT02857998)</u> – In 2016 and 2017, we initiated Phase I studies of HMPL-523 in hematological cancer in Australia and China respectively which to-date in dose escalation and expansion have enrolled over 150 non-Hodgkin's lymphoma patients. Since early 2018, we have been increasing the number of active clinical sites, in Australia and China to support a large dose expansion program in a broad range of hematological cancers. We intend to use safety and efficacy data from these Phase I/Ib dose escalation/expansion studies in B-cell malignancies to guide the registration strategy in China during late 2019.

<u>Phase I study of HMPL-523 in indolent non-Hodgkin's lymphoma (NCT03779113)</u> – Our IND applications for HMPL-523 were cleared in the U.S. in mid-2018 and Europe in early-2019, multiple sites are now initiated and patient screening is underway. We anticipate treatment of our first indolent non-Hodgkin's lymphoma patients, in this Phase I dose escalation study, in the U.S. and Europe in the second half of 2019.

<u>Phase I study of HMPL-523 in combination with Vidaza<sup>®</sup> in acute myeloid leukemia (NCT03483948)</u> – In October 2018, we initiated a Phase I study of HMPL-523 in combination with Vidaza<sup>®</sup> (azacitidine), an approved hypomethylating agent, in elderly patients with acute myeloid leukemia in China. This is a Phase I, open-label, multicenter study to evaluate the safety, pharmacokinetics ("PK") and preliminary efficacy of the combination in previously untreated elderly patients with acute myeloid leukemia. The primary outcome measure is safety with a secondary endpoint of efficacy. The two-stage study will have a dose escalation and dose expansion stage.

<u>Phase I/Ib study of HMPL-523 in patients with immune thrombocytopenia purpura ("ITP")</u> – We are also considering immunology applications for HMPL-523 including ITP, an autoimmune disorder characterized by low platelet count and an increased bleeding risk. Despite availability of several treatments with differing mechanisms of action, a significant proportion of patients develop resistance to treatment and are prone to relapse. There is also a significant population of patients who have limited sensitivity to currently available agents and are in need of a new approach to treatment. A Phase I/Ib study in ITP in China is now screening patients for enrollment.

# HMPL-689

HMPL-689 is a novel, highly selective and potent small molecule inhibitor targeting the isoform PI3K $\delta$ , a key component in the B-cell receptor signaling pathway. We have designed HMPL-689 with superior PI3K $\delta$  isoform selectivity than currently available agents. HMPL-689's PK properties are favorable with good oral absorption, moderate tissue distribution and low clearance in preclinical PK studies. We also expect that HMPL-689 will have low risk of drug accumulation and drug-to-drug interaction.

We currently retain all rights to HMPL-689 worldwide. The table below shows a summary of the clinical studies for HMPL-689.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-689 monotherapy	Healthy volunteers	Australia	Ι	Completed	NCT02631642
HMPL-689 monotherapy	Indolent non-Hodgkin's lymphoma	US/EU	Ι	In planning	NCT03786926
HMPL-689 monotherapy	Indolent non-Hodgkin's lymphoma	China	Ib	Enrolling	NCT03128164

In 2016, we completed a Phase I, first-in-human, dose escalation study in healthy adult volunteers in Australia to evaluate the pharmacokinetics and safety profile following single oral dosing HMPL-689. Results were as expected with linear pharmacokinetics properties and tolerable safety profile. In late 2017, we initiated a Phase I dose escalation study in patients with hematologic malignancies and have recently completed selection of a recommended Phase II dose. We are now conducting a Phase Ib expansion in China; and have also opened clinical sites in the U.S. and Europe in order to start a Phase I study this year.

# **EPITINIB (HMPL-813)**

Epitinib is a potent and highly selective oral EGFR inhibitor which has demonstrated brain penetration and efficacy in both pre-clinical and clinical studies. Epitinib is designed to improve blood-brain barrier penetration of the drug, allowing for high drug exposure in the brain. We currently retain all rights to epitinib worldwide. The table below shows a summary of the clinical studies for epitinib.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Epitinib monotherapy	Glioblastoma	China	Ib/II	Enrolling	NCT03231501
Epitinib monotherapy	EGFR-mutation NSCLC with brain metastasis	China	Ib	Completed	NCT02590952

<u>Glioblastoma</u>: Glioblastoma is a very aggressive disease with poor prognosis. There are currently no targeted therapies approved for glioblastoma. EGFR gene amplification has been identified in about half of glioblastoma patients, according to The Cancer Genome Atlas Research Network, and hence is a potential therapeutic target in glioblastoma. In March 2018, we initiated a Phase Ib/II, multi-center, single-arm, open-label study to evaluate the efficacy and safety of epitinib as a monotherapy in patients with EGFR gene amplified, histologically confirmed glioblastoma. Enrollment is ongoing.

# HMPL-453

HMPL-453 is a highly selective and potent, small molecule that targets FGFR 1/2/3, a sub-family of receptor tyrosine kinases. A growing body of evidence has demonstrated the oncogenic potential of FGFR aberrations in driving tumor growth, promoting angiogenesis, and conferring resistance mechanisms to oncology therapies. Targeting the FGF/FGFR signaling pathway has therefore attracted attention from biopharmaceutical companies and has become an important exploratory target for new anti-tumor target therapies. We currently retain all rights to HMPL-453 worldwide. The table below shows a summary of the clinical studies for HMPL-453.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-453 monotherapy	Solid tumors	China	I	Enrolling	NCT03160833

In June 2017, we initiated a Phase I clinical trial of HMPL-453 in China. This Phase I study is a multi-center, single-arm, open-label, two-stage study to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy of HMPL-453 monotherapy in patients with solid tumors harboring FGFR genetic alterations. Enrollment is ongoing and planning for further development is underway.

# THELIATINIB (HMPL-309)

Theliatinib is a novel small molecule EGFR inhibitor. Tumors with wild-type EGFR activation, for instance, through gene amplification or protein over-expression, are less sensitive to EGFR TKIs such as Iressa<sup>®</sup> and Tarceva<sup>®</sup> due to sub-optimal binding affinity. Theliatinib was designed with strong affinity to the wild-type EGFR kinase and has demonstrated five to ten times the potency than Tarceva<sup>®</sup> in pre-clinical trials. As a result, we believe that theliatinib could potentially be more effective than existing EGFR TKI products and benefit patients with tumor types with high incidence of wild-type EGFR activation.

We currently retain all rights to theliatinib worldwide. Phase I/Ib studies of theliatinib are complete and we are now looking at alternative uses of theliatinib and could consider the potential for use in combinations with immunotherapy.

# DISCOVERY RESEARCH & PRECLINICAL DEVELOPMENT

We continue to create differentiated novel oncology and immunology treatments with global potential.

These novel drug candidates reflect our core R&D philosophy in treating cancer and immunological diseases through multiple modalities and mechanisms. These include furthering pre-clinical programs for therapies addressing aberrant genetic drivers, inactivated T-cell response, and insufficient T-cell response. The aim of our in-house discovery organization is to submit a novel drug candidate for clinical development each year or so.

Importantly, we will continue to design drug candidates with profiles that enable them to be used in innovative combinations with other selective inhibitors, chemotherapy agents and immunotherapies. Such combination



therapies enable treatment of cancer via multiple pathways and modalities simultaneously, which has the potential to significantly improve treatment outcomes.

In June 2019 we submitted an IND application to the NMPA for HMPL-306, a novel small molecule dual-inhibitor of IDH 1 and 2 enzymes. IDH1 and IDH2 mutations have been implicated as drivers of certain hematological malignancies, gliomas and solid tumors, particularly amongst acute myeloid leukemia (AML) patients.

# COMMERCIAL PLATFORM

Our Commercial Platform is a large-scale, high-performance drug marketing and distribution platform covering over 330 cities and towns in China with approximately 3,300 sales personnel. It targets multiple therapeutic areas with several household-name brands. Built over the past 18 years, it is focused on two main business areas.

First, our Prescription Drugs business is a higher-margin/profit business operated through our joint ventures Hutchison Sinopharm and SHPL, in which we nominate management and run the day-to-day operations. Aspects of our Prescription Drugs business form a core strategic platform that we plan to use to launch our Innovation Platform drugs once approved in China. Second, our Consumer Health business is a profitable and cash flow generating business primarily selling market-leading, household-name over-the-counter ("OTC") pharmaceutical products through our non-consolidated joint venture HBYS.

During the first half of 2019, global macroeconomic factors including, but not limited to, the trade discussions between the United States and China contributed to a 6% depreciation in the value of the RMB against the U.S. dollar versus H1 2018. As a result, in addition to reporting changes in performance in our normal U.S. dollar method, we also report changes in performance at constant exchange rate (CER) which is a non-GAAP measure. Please refer to "Use of Non-GAAP Financial Measures and Reconciliation" below for further information relevant to the interpretation of these financial measures and reconciliations of these financial measures to the most comparable GAAP measures.

During the first half of 2019, the Commercial Platform delivered continued solid growth in sales and net income growth on a CER basis. Consolidated sales of our Commercial Platform's subsidiaries grew by 2% (7% at CER) to \$90.2 million (H1-18: \$88.6m). The sales of our Commercial Platform's non-consolidated joint ventures, SHPL and HBYS, also grew by 2% (8% at CER) to \$276.9 million (H1-18: \$271.7m). This resulted in consolidated net income attributable to Chi-Med from our Commercial Platform up 3% (9% at CER) to \$27.7 million (H1-18: \$26.9m).

# **PRESCRIPTION DRUGS BUSINESS:**

In H1 2019, consolidated sales of our Prescription Drugs subsidiaries increased by 7% (13% at CER) to \$72.6 million (H1-18: \$68.0m), despite the halt of the Seroquel<sup>®</sup> business as detailed below. The consolidated net income attributable to Chi-Med from our Prescription Drugs business was up 5% (11% at CER) to \$21.8 million (H1-18: \$20.8m). The Prescription Drugs business represented 79% of our overall Commercial Platform net income in H1 2019 (H1-18: 77%).

**SHPL:** Our own-brand Prescription Drugs business, operated through our non-consolidated joint venture SHPL, is a well-established large-scale business. In H1 2019, SHPL delivered sales growth of 4% (10% at CER) at \$158.9 million (H1-18: \$152.7m), as a result of both volume and price growth on SXBX pill.

*SXBX pill*: SHPL's main product is SXBX pill, an oral vasodilator and pro-angiogenesis prescription therapy approved to treat coronary artery disease, which includes stable/unstable angina, myocardial infarction and sudden cardiac death. There are over one million deaths due to coronary artery disease per year in China, with this number set to rise due to an aging population with high levels of smoking (28% of adults), increasing levels of obesity (30% of adults are overweight) and hypertension (25% of adults). SXBX pill is the third largest botanical prescription drug in this indication in China, with market share in 2018 of 17.0% (2017: 15.4%) nationally and 48.0% (2017: 47.0%) in Shanghai.

Sales of SXBX pill have grown more than twenty-fold since 2001 due to continued geographical expansion of sales coverage, including 9% (15% at CER) to \$141.0 million in H1 2019 (H1-18: \$129.8m).

SXBX pill is protected by a formulation patent that expires in 2029 and is one of less than two dozen proprietary prescription drugs represented on China's National Essential Medicines List, which means that all Chinese

state-owned health care institutions are required to carry the drug. SXBX pill is a low-cost drug, fully reimbursed in all provinces in China, listed on China's Low Price Drug List with an average daily cost of RMB4.52 (H1-18: RMB4.17), or approximately \$0.67.

In January 2019, SHPL was awarded the 2018 State Scientific and Technological Progress Award ("SSTPA") – Second Prize, which was presented by President Xi Jinping, Premier Li Keqiang and other state leaders of the PRC at the National Science and Technology Awards Ceremony. The award was given for a study, conducted by SHPL and several academic and medical institutions in China, on the basis of the substance, mechanism of action, clinical evidence and production chain control of SXBX pill. This SHPL award was one of only two such SSTPA awards given this year to studies in the botanical drug industry.

The SHPL operation is large-scale in both the commercial and manufacturing areas. The commercial team now has about 2,400 medical sales representatives which allows for the promotion and scientific detailing of our prescription drug products not just in hospitals in provincial capitals and medium-sized cities, but also in the majority of county-level hospitals in China.

SHPL's GMP-certified factory located 40 kilometers south of Shanghai in Fengpu district holds 74 drug product manufacturing licenses and is operated by about 540 manufacturing staff. This factory, opened in 2017, has approximately tripled SHPL's capacity and therefore positions us well for continued long-term growth.

*Concor*<sup>®</sup>: Concor<sup>®</sup> (Bisoprolol tablets) is a cardiac beta1-receptor blocker, relieving hypertension and reducing high blood pressure. Concor<sup>®</sup> is the number two beta-blocker in China in 2018 with an approximately 24% (2017: 18%) national market share in China's beta-blocker drug market and 63% of China's generic bisoprolol market. In early 2019, we re-structured our collaboration agreement with Merck Serono on Concor<sup>®</sup>, making territorial adjustments and expanding SHPL operations on Concor<sup>®</sup> into nine provinces in China (2018: six), markets that contain about 600 million people.

**Hutchison Sinopharm:** Our Prescription Drugs commercial services business, which in addition to commercializing certain of our own products, provides distribution and marketing services to third-party pharmaceutical companies in China. In H1 2019, Hutchison Sinopharm sales grew by 7% (13% at CER) to \$72.6 million (H1-18: \$68.0m) as a result of broad scale expansion which was partially offset by the halt of Seroquel<sup>®</sup> commercial operations.

Hutchison Sinopharm has a dedicated team of over 200 commercial staff focused on three key areas of operation.

Firstly, a commercial team that markets over 700 third-party prescription drug products directly to over 360 public and private hospitals in the Shanghai region and through a network of 50 distributors to cover all other provinces in China.

Second, a commercial team that markets Chi-Med's own science-based infant nutrition products in over 8,000 outlets in China and through a Customer Relationship Management network with over 23,000 promoters and over 200,000 members.

Third, during the second half of 2018 we began establishing an oncology commercial organization within Hutchison Sinopharm, which is cross-charged in full to the Innovation Platform. The oncology team, which currently has about 60 dedicated staff covering 25 provinces in China, is focused on medical affairs activities to support enrollment of our Innovation Platform clinical studies in China as well as preparation for the potential upcoming commercial launch of surufatinib late next year. Given the strategic importance of this activity, we are now preparing to move the oncology commercial organization into our 99.8%-owned Innovation Platform.

*Seroquel*<sup>®</sup> *update:* Seroquel<sup>®</sup> (quetiapine tablets) is an anti-psychotic therapy approved for bi-polar disorder and schizophrenia. Since early 2015, Hutchison Sinopharm has been the exclusive marketing agent for Seroquel<sup>®</sup> tablets in China. In June 2018, AstraZeneca sold and licensed its rights to Seroquel<sup>®</sup> to Luye Pharma Group, Ltd., including its rights in China. The terms of our agreement with AstraZeneca were assigned to Luye Pharma Hong Kong Ltd. ("Luye HK"). In May 2019, we received a notice from Luye HK purporting to terminate our agreement. We believe that Luye HK has no basis for termination and intend to vigorously enforce our rights under the current agreement. During 2018 and the first half of 2019, net income from our Seroquel<sup>®</sup> business represented approximately 4.0% (\$1.7m) and 1.3% (\$0.4m) respectively of the net income attributable to Chi-Med from our Commercial Platform.

# CONSUMER HEALTH BUSINESS:

In H1 2019, sales of our Consumer Health subsidiaries decreased by 15% (13% at CER) to \$17.6 million (H1-18: \$20.6m) due primarily to rationalization of certain low contribution products. The consolidated net income attributable to Chi-Med from our Consumer Health business was down 4% (up 2% at CER) to \$5.9 million (H1-18: \$6.1m). The Consumer Health business represented 21% of our overall Commercial Platform net income in H1 2019 (H1-18: 23%).

**HBYS:** Our primarily OTC business operated through our non-consolidated joint venture, HBYS, focuses on the manufacture, marketing and distribution of OTC and certain prescription pharmaceutical products. In H1 2019, HBYS sales fell 1% (up 5% at CER) to \$118.0 million (H1-18: \$119.0m), as a result of a decrease in sales of Fu Fang Dan Shen ("FFDS") due to heightened competitive activity, offset by the increase of sales of our second wave products.

Its Bai Yun Shan brand is a market-leading, household name, established over 40 years ago, and is known by the majority of Chinese consumers. In addition to about 1,000 manufacturing staff in Guangdong and Anhui and 185 drug product licenses, HBYS has a commercial team of about 900 sales staff that covers the national retail pharmacy channel in China.

*FFDS tablets and Banlangen granules:* FFDS tablets (angina) and Banlangen granules (anti-viral cold/flu), the two main products of HBYS, are generic OTC drugs with leading national market share in 2018 in China of 38% (2017: 38%) and 54% (2017: 53%), respectively. In H1 2019, the combined sales of these products decreased by 6% (0% at CER) at \$66.4 million (H1-18: \$70.7m). Banlangen sales were down 1% (up 6% at CER) to \$37.7 million (H1-18: \$37.9m) as a result of a similar flu season to early 2018. FFDS sales were down 13% (7% at CER) to \$28.7 million (H1-18: \$32.8m) due to heightened competitive activity.

Given the relative market maturity, and highly competitive environment, for FFDS and Banlangen, HBYS has invested significant resources in recent years into building out a second wave of products. These products, including Nao Xin Qing tablets (cerebrovascular diseases) and Kou Yan Qing granules (periodontitis), made solid progress during the first half of 2019 growing 20% (28% at CER) to \$33.5 million (H1-18: \$27.8m).

*HBYS property update:* HBYS's vacant Plot 2 (26,700 sqm.) in Guangzhou has been listed for sale as part of the Guangzhou municipal government's urban redevelopment scheme plan for three years. We expect the auction value for Plot 2 to be well over \$100 million of which 40 to 50% would be paid to HBYS as compensation for return of the land use rights. In addition, the move away from HBYS's larger Plot 1 (59,400 sqm.) will be contingent on how the Bozhou factory develops, but, when auctioned, we anticipate that based on recent precedent land transactions, Plot 1 could bring HBYS compensation per square meter comparable to Plot 2.

**Hutchison Healthcare Limited ("HHL") and Hutchison Hain Organic Holdings Limited ("HHOH"):** HHL, HHOH and other minor entities are subsidiaries involved in the commercialization of health-related consumer products. Sales of such products in H1 2019 decreased by 15% (13% at CER) to \$17.6 million (H1-18: \$20.6m) resulting from a rationalization of certain low contribution products primarily under HHOH.

# Commercial Platform dividends:

The profits of the Commercial Platform continue to pass on to the Chi-Med Group through dividend payments primarily from our non-consolidated joint ventures, SHPL and HBYS. Dividends of \$18.2 million (H1-18: \$23.5m) were paid from these joint ventures to the Chi-Med Group level during the first half of 2019. Net income from SHPL and HBYS have totaled over \$600 million since 2005, of which \$423 million has been declared in dividends to Chi-Med and its partners, with the balance retained by the joint ventures as cash or used primarily to fund factory upgrades and expansion. As of June 30, 2019, SHPL and HBYS held in aggregate \$47.3 million in cash and cash equivalents, with no outstanding bank borrowings.

Christian Hogg Chief Executive Officer July 30, 2019

# USE OF NON-GAAP FINANCIAL MEASURES AND RECONCILIATION

In addition to financial information prepared in accordance with U.S. GAAP, this announcement also contains certain non-GAAP financial measures based on management's view of performance including:

- Adjusted R&D expenses;
- Adjusted Group net cash flows and adjusted Group net cash flows excluding financing activities; and
- CER.

Management uses such measures internally for planning and forecasting purposes and to measure the Chi-Med Group's overall performance. We believe these adjusted financial measures provide useful and meaningful information to us and investors because they enhance investors' understanding of the continuing operating performance of our business and facilitate the comparison of performance between past and future periods. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. Other companies may define these measures in different ways.

Adjusted R&D expenses: We exclude the impact of the revenue received from external customers and cost of goods of our Innovation Platform, which is reinvested into our clinical trials, to derive our adjusted R&D expenses. Revenue received from external customers of our Innovation Platform consists of milestone and other payments from our collaboration partners. The variability of such payments makes the identification of trends in our ongoing R&D activities more difficult. We believe the presentation of adjusted R&D expenses provides useful and meaningful information about our ongoing R&D activities by enhancing investors' understanding of the scope of our normal, recurring operating R&D expenses.

Adjusted Group net cash flows and adjusted Group net cash flows excluding financing activities: We include the change in short-term investments for the period to the change in cash and cash equivalents for the period to derive our adjusted Group net cash flows, and exclude the net cash (used in)/generated from financing activities for the period to derive our adjusted Group net cash flows excluding financing activities. We believe the presentation of adjusted Group net cash flows and adjusted Group net cash flows excluding financing activities provides useful and meaningful information about the use of our cash resources.

*CER:* We remove the effects of currency movements from period-to-period comparisons by retranslating the current period's performance at previous period's foreign currency exchange rates. Because we have significant operations in China, the RMB to U.S. dollar exchange rates used for translation may have a significant effect on our reported results. We believe the presentation at CER provides useful and meaningful information because it facilitates period-to-period comparisons of our results and increases the transparency of our underlying performance.

#### \$'millions Six Months Six Months **Ended June Ended June** 30, 2019 30.2018 Segment operating loss – Innovation Platform (63.9)(53.1)Less: Segment revenue from external customers - Innovation Platform (12.0)(13.6)Add: Cost of goods - third parties 1.4 Adjusted R&D expenses (74.5)(66.7)

# Reconciliation of GAAP to adjusted R&D expenses:

Reconciliation of GAAP change in cash and cash equivalents and short-term investments to Adjusted Group net cash flows excluding financing activities:

\$'millions	H1 2019	2019 Current Guidance	2019 Previous Guidance
Cash and cash equivalents and short-term investments at end of period	237.3	180-210*	150-180*
Less: Cash and cash equivalents and short-term investments at beginning of year	(301.0)	(300)	(300)
Adjusted Group net cash flows Add: Net cash used in financing activities for the	(63.7) 29.5	(90)-(120) *	(120)-(150) *
period Adjusted Group net cash flows excluding financing activities	(34.2)	(90)-(120)	(120)-(150)

\* For the purposes of this reconciliation, 2019 guidance for net cash used in or generated from financing activities for the year is not provided and as such, cash and cash equivalents and short-term investments at the end of year excludes the effect of any net cash used in or generated from financing activities for the year.

# Reconciliation of GAAP sales and net income attributable to Chi-Med—Commercial Platform to CER:

\$'millions (except %)	-	onths ded	Gr	Growth Amount			Growth %	
	June 30, 2019	June 30, 2018	Actual	CER	Exchange effect	Actual growth %	CER growth %	Exchange effect %
Consolidated sales								
Commercial Platform	90.2	88.6	1.6	6.4	(4.8)	2%	7%	-5%
<ul> <li>Prescription Drugs</li> </ul>	72.6	68.0	4.6	9.1	(4.5)	7%	13%	-6%
— Consumer Health	17.6	20.6	(3.0)	(2.7)	(0.3)	-15%	-13%	-2%
Non-consolidated joint			( )	. ,	· · ·			
venture sales	276.9	271.7	5.2	22.3	(17.1)	2%	8%	-6%
— SHPL	158.9	152.7	6.2	15.8	(9.6)	4%	10%	-6%
— HBYS	118.0	119.0	(1.0)	6.5	(7.5)	-1%	5%	-6%
Consolidated net income attributable to Chi-Med	)							
Commercial Platform	27.7	26.9	0.8	2.4	(1.6)	3%	9%	-6%
<ul> <li>Prescription Drugs</li> </ul>	21.8	20.8	1.0	2.3	(1.3)	5%	11%	-6%
— Consumer Health	5.9	6.1	(0.2)	0.1	(0.3)	-4%	2%	-6%
Sales of Key Products								
— SXBX pill	141.0	129.8	11.2	19.7	(8.5)	9%	15%	-6%
— FFDS and Banlangen	66.4	70.7	(4.3)	(0.2)	(4.1)	-6%	0%	-6%
— FFDS	28.7	32.8	(4.1)	(2.3)	(1.8)	-13%	-7%	-6%
— Banlangen	37.7	37.9	(0.2)	2.1	(2.3)	-1%	6%	-7%
— Nao Xin Qing and Kou	0.11	0.10	()		()	. /0	070	. /0
Yan Qing	33.5	27.8	5.7	7.7	(2.0)	20%	28%	-8%

CHI-(MED)

# INTERIM UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### Hutchison China MediTech Limited Condensed Consolidated Balance Sheets (in US\$'000, except share data)

	Note	June 30, 2019	December 31, 2018
		(Unaudited)	
Assets			
Current assets			
Cash and cash equivalents	3	83,360	86,036
Short-term investments	4	153,928	214,915
Accounts receivable—third parties	5	42,758	40,176
Inventories	6	14,223	12,309
Other current assets		15,227	17,105
Total current assets		309,496	370,541
Property, plant and equipment		17,669	16,616
Right-of-use assets	7	6,792	—
Investments in equity investees	8	146,977	138,318
Deferred issuance costs		7,506	—
Other assets		6,774	6,643
Total assets		495,214	532,118
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	9	26,145	25,625
Other payables, accruals and advance receipts	10	75,567	56,327
Lease liabilities	7	3,529	_
Other current liabilities		5,364	3,527
Total current liabilities		110,605	85,479
Lease liabilities	7	3,714	
Long-term bank borrowings	11	_	26,739
Other liabilities		7,858	7,645
Total liabilities		122,177	119,863
Commitments and contingencies	12		
Company's shareholders' equity			
Ordinary shares; \$0.10 par value; 1,500,000,000 shares authorized; 666,577,450 and 666,577,450 shares issued at June 30, 2019 and			
December 31, 2018 respectively	13	66,658	66,658
Additional paid-in capital		510,699	505,585
Accumulated losses		(229,067)	(183,004)
Accumulated other comprehensive loss		(400)	(243)
Total Company's shareholders' equity		347,890	388,996
Non-controlling interests		25,147	23,259
Total shareholders' equity		373,037	412,255
Total liabilities and shareholders' equity		495,214	532,118

The accompanying notes are an integral part of these interim unaudited condensed consolidated financial statements.

# Hutchison China MediTech Limited Condensed Consolidated Statements of Operations (Unaudited, in US\$'000, except share and per share data)

		Six Months June 30	
	Note	2019	2018
Revenues			
Goods —third parties		86,858	79,463
-related parties	17(i)	3,732	3,449
Services —commercialization—third parties		2,584	5,653
-collaboration research and development-third			
parties		7,056	8,548
—research and development—related parties	17(i)	252	5,076
Other collaboration revenue—royalties—third parties		1,715	_
Total revenues	15	102,197	102,189

Operating expenses			
Costs of goods—third parties		(74,051)	(65,422)
Costs of goods—related parties		(2,610)	(2,455)
Costs of services—commercialization—third parties		(1,929)	(4,001)
Research and development expenses	16	(69,287)	(60,053)
Selling expenses		(7,501)	(9,392)
Administrative expenses		(18,830)	(14,549)
Total operating expenses		(174,208)	(155,872)
Loss from operations		(72,011)	(53,683)
Other income, net of other expenses		3,710	3,188
Loss before income taxes and equity in earnings of equity			
investees		(68,301)	(50,495)
Income tax expense	18	(2,462)	(2,680)
Equity in earnings of equity investees, net of tax	8	27,308	23,050
Net loss		(43,455)	(30,125)
Less: Net income attributable to non-controlling interests		(1,914)	(2,566)
Net loss attributable to the Company		(45,369)	(32,691)
Losses per share attributable to the Company—basic and diluted (US\$ per share)	19	(0.07)	(0.05)
Number of shares used in per share calculation—basic and diluted	19	665,553,637	663,894,540

Note: The losses per share attributable to the Company—basic and diluted presented were adjusted retroactively for each of the six months ended June 30, 2019 and 2018 to take into account the share split approved by ordinary resolution at the Extraordinary General Meeting of the Company held on May 29, 2019, pursuant to which each ordinary share was subdivided into 10 ordinary shares with effect from May 30, 2019.

The accompanying notes are an integral part of these interim unaudited condensed consolidated financial statements.

### Hutchison China MediTech Limited Condensed Consolidated Statements of Comprehensive Loss (Unaudited, in US\$'000)

	Six Months E June 30	
	2019	2018
Net loss	(43,455)	(30,125)
Other comprehensive income		
Foreign currency translation (loss)/gain	(179)	3,445
Total comprehensive loss	(43,634)	(26,680)
Less: Comprehensive income attributable to non-controlling interests	(1,892)	(2,870)
Total comprehensive loss attributable to the Company	(45,526)	(29,550)

The accompanying notes are an integral part of these interim unaudited condensed consolidated financial statements.

### Hutchison China MediTech Limited Condensed Consolidated Statements of Changes in Shareholders' Equity (Unaudited, in US\$'000, except share data in '000)

	Ordinary Shares Number	Ordinary Shares Value	Additional Paid-in Capital	Accumulated Losses	Accumulated Other Comprehensive Income/(Loss)	Total Company's Shareholders' Equity	Non- controlling Interests	Total Shareholders' Equity
As at January 1, 2018	664,470	66,447	496,960	(108,184)	5,430	460,653	23,230	483,883
Net (loss)/income	—	—	—	(32,691)	—	(32,691)	2,566	(30,125)
Issuances in relation to share option exercises	856	86	634	_	_	720	_	720
Share-based compensation								
Share options	_	_	2,784	_	_	2,784	7	2,791
Long-term incentive plan ("LTIP")			2,575			2,575	7	2,582
	_	_	5,359	_	_	5,359	14	5,373

LTIP—treasury shares acquired and held by								
Trustee	_	_	(5,451)	_	_	(5,451)		(5,451)
Transfer between reserves	_	_	15	(15)	_	_	_	
Foreign currency translation								
adjustments					3,141	3,141	304	3,445
As at June 30, 2018	665,326	66,533	497,517	(140,890)	8,571	431,731	26,114	457,845
As at December 31, 2018	666,577	66,658	505,585	(183,004)	(243)	388,996	23,259	412,255
Impact of change in								
accounting policy (Note 2)				(655)		(655)	(16)	(671)
As at January 1, 2019	666,577	66,658	505,585	(183,659)	(243)	388,341	23,243	411,584
Net (loss)/income	—	—	—	(45,369)	—	(45,369)	1,914	(43,455)
Share-based compensation								
Share options	—	—	4,118		—	4,118	9	4,127
LTIP		_	1,303	_	—	1,303	3	1,306
	—	—	5,421	_	—	5,421	12	5,433
LTIP—treasury shares								
acquired and held by								
Trustee	_	_	(346)	_	_	(346)	_	(346)
Transfer between reserves	—	—	39	(39)	—	—	—	—
Foreign currency translation								
adjustments					(157)	(157)	(22)	(179)
As at June 30, 2019	666,577	66,658	510,699	(229,067)	(400)	347,890	25,147	373,037

The accompanying notes are an integral part of these interim unaudited condensed consolidated financial statements.

#### Hutchison China MediTech Limited Condensed Consolidated Statements of Cash Flows (Unaudited, in US\$'000)

		Six Months June 3	
	Note	2019	2018
Net cash used in operating activities	21	(30,045)	(18,596)
Investing activities			
Purchases of property, plant and equipment		(3,848)	(2,079)
Deposits in short-term investments		(329,102)	(491,169)
Proceeds from short-term investments		390,089	517,035
Investment in an equity investee		—	(8,000)
Net cash generated from investing activities		57,139	15,787
Financing activities	_		
Proceeds from issuance of ordinary shares	14(i)	_	720
Purchases of treasury shares	14(ii)	(346)	(5,451)
Dividends paid to non-controlling shareholders of subsidiaries	17(iii)	(1,282)	_
Proceeds from bank borrowings	11	_	26,923
Repayment of bank borrowings	11	(26,923)	(30,000)
Payment of issuance costs		(964)	(34)
Net cash used in financing activities		(29,515)	(7,842)
Net decrease in cash and cash equivalents		(2,421)	(10,651)
Effect of exchange rate changes on cash and cash equivalents		(255)	715
	_	(2,676)	(9,936)
Cash and cash equivalents			
Cash and cash equivalents at beginning of period		86,036	85,265
Cash and cash equivalents at end of period	_	83,360	75,329

The accompanying notes are an integral part of these interim unaudited condensed consolidated financial statements.

# Hutchison China MediTech Limited

# Notes to the Interim Unaudited Condensed Consolidated Financial Statements

# 1. Organization and Nature of Business

Hutchison China MediTech Limited (the "Company") and its subsidiaries (together the "Group") are principally engaged in researching, developing, manufacturing and selling pharmaceuticals and healthcare products. The Group and its equity investees have research and development facilities and manufacturing plants in the People's Republic of China (the "PRC") and sell their products mainly in the PRC and Hong Kong.

#### Liquidity

As at June 30, 2019, the Group had accumulated losses of US\$229,067,000 primarily due to its spending in drug research and development ("Drug R&D") activities. The Group regularly monitors current and expected liquidity requirements to ensure that it maintains sufficient cash balances and adequate credit facilities to meet its liquidity requirements in the short and long term. As at June 30, 2019, the Group had cash and cash equivalents of US\$83,360,000, short-term investments of US\$153,928,000 and unutilized bank borrowing facilities of US\$146,282,000. Short-term investments comprised of bank deposits maturing over three months. The Group's operating plan includes the continued receipt of dividends from certain of its equity investees. Dividends received from equity investees for the six months ended June 30, 2019 and 2018 were US\$18,173,000 and US\$23,526,000 respectively.

Based on the Group's operating plan, the existing cash and cash equivalents, short-term investments and unutilized bank borrowing facilities are considered to be sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months (the look-forward period used).

#### 2. Summary of Significant Accounting Policies

#### Principles of Consolidation and Basis of Presentation

The interim unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements, except for the adoption of Accounting Standards Codification ("ASC") 842, Leases ("ASC 842") as described below. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair statement of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The comparative year-end condensed balance sheet data was derived from the annual audited consolidated financial statements, but is condensed to the same degree as the interim condensed balance sheet data.

The interim unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users have read or have access to the annual audited consolidated financial statements for the preceding fiscal year.

The preparation of interim unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the interim unaudited condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used in determining items such as useful lives of property, plant and equipment, write-down of inventories, allowance for doubtful accounts, share-based compensation, impairments of long-lived assets, impairment of other intangible asset and goodwill, income tax expenses, tax valuation allowances, revenues and cost accruals from research and development projects. Actual results could differ from those estimates.

#### Leases

#### Summary of impact of applying ASC 842

The Group applied ASC 842 to its various leases at the date of initial application of January 1, 2019. As a result, the Group has changed its accounting policy for leases as detailed below. The core principle of ASC 842 is that a lessee should recognize the assets and liabilities that arise from leases. Therefore, the Group recognizes in the condensed consolidated balance sheets liabilities to make lease payments (the lease liabilities) and right-of-use assets representing its right to use the underlying assets for their lease terms. The Group applied ASC 842 using the optional transition method by recognizing the cumulative effect as an adjustment to opening accumulated losses as at January 1, 2019. The comparative information prior to January 1, 2019 has not been adjusted and continues to be reported under ASC 840, Leases ("ASC 840").

The Group assessed lease agreements as at January 1, 2019 under ASC 842, except for short-term leases. The Group elected the short-term lease exception for leases with a term of 12 months or less and

recognizes lease expenses for such leases on a straight-line basis over the lease term and does not recognize right-of-use assets or lease liabilities accordingly. As a result of this assessment, the Group recorded an aggregate US\$0.7 million in additional lease expenses as a cumulative adjustment to opening accumulated losses upon adoption. Additionally, the Group recognized right-of-use assets and lease liabilities of US\$5.7 million and US\$6.4 million respectively as at January 1, 2019.

The lease liabilities were measured at the present value of the remaining lease payments, discounted using the lessees' incremental borrowing rate as at January 1, 2019. The Group's weighted average incremental borrowing rate applied on January 1, 2019 was 3.97% per annum.

A reconciliation of the Group's reported operating lease commitments as at December 31, 2018 and the Group's lease liabilities recognized upon adoption of ASC 842 as at January 1, 2019 is as follows:

	(in US\$'000)
Operating lease commitments as at December 31, 2018 (note (a))	8,835
Less: Leases not commenced as at January 1, 2019	(3,676)
Less: Short-term leases	(5)
Add: Adjustment as a result of the treatment for a termination option (note (b))	1,409
Less: Discount under the lessees' incremental borrowing rate as at January 1, 2019	(206)
Lease liabilities recognized as at January 1, 2019	6,357

#### Notes:

(a) Future aggregate minimum payments under non-cancellable operating leases under ASC 840 were as follows:

	December 31, 2018
	(in US\$'000)
Not later than 1 year	3,026
Between 1 to 2 years	2,735
Between 2 to 3 years	1,056
Between 3 to 4 years	882
Between 4 to 5 years	810
Later than 5 years	326
Total minimum lease payments	8,835

(b) The Group leases its corporate offices in Hong Kong through a support service agreement with an indirect subsidiary of CK Hutchison Holdings Limited ("CK Hutchison"), which is the Company's ultimate holding company. The support service agreement may be terminated by giving 3-month advance notice; therefore, there was no lease commitment beyond the 3-month advance notice period as at December 31, 2018. This termination option is not considered probable of exercise for the purposes of applying ASC 842.

The Group recognized right-of-use assets as at January 1, 2019 measured at their carrying amounts as if ASC 842 had been applied since their commencement dates, but discounted using the lessees' incremental borrowing rate as at January 1, 2019.

Recognized right-of-use assets upon adoption were as follows:

	(in US\$'000)
Offices	4,877
Factories	383
Others	487
	5,747

There were no adjustments to net cash generated from/(used in) operating activities, investing activities or financing activities in the condensed consolidated statement of cash flows.

In applying ASC 842 for the first time, the Group has used the following practical expedients permitted by the standard: (i) no reassessment of whether any expired or existing contracts are or contain leases; (ii) no reassessment of the lease classification for any expired or existing leases; (iii) the exclusion of initial direct costs for the measurement of the right-of-use assets at the date of initial application; and (iv) the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

#### Updated accounting policy—ASC 842

In an operating lease, a lessee obtains control of only the use of the underlying asset, but not the underlying asset itself. An operating lease is recognized as a right-of-use asset with a corresponding liability at the date which the leased asset is available for use by the Group. The Group recognizes an obligation to make lease payments equal to the present value of the lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Group will exercise that option.

Lease liabilities include the net present value of the following lease payments: (i) fixed payments; (ii) variable lease payments; and (iii) payments of penalties for terminating the lease if the lease term reflects the lessee exercising that option, if any. Lease liabilities exclude the following payments that are generally accounted for separately: (i) non-lease components, such as maintenance and security service fees and value added tax, and (ii) any payments that a lessee makes before the lease commencement date. The lease payments are discounted using the interest rate implicit in the lease or if that rate cannot be determined, the lessee's incremental borrowing rate being the rate that the lessee would have to pay to borrow the funds in its currency and jurisdiction necessary to obtain an asset of similar value, economic environment and terms and conditions.

An asset representing the right to use the underlying asset during the lease term is recognized that consists of the initial measurement of the operating lease liability, any lease payments made to the lessor at or before the commencement date less any lease incentives received, any initial direct cost incurred by the Group and any restoration costs.

After commencement of the operating lease, the Group recognizes lease expenses on a straight-line basis over the lease term. The right-of-use asset is subsequently measured at cost less accumulated amortization and any impairment provision. The amortization of the right-of-use asset represents the difference between the straight-line lease expense and the accretion of interest on the lease liability each period. The interest amount is used to accrete the lease liability and to amortize the right-of-use asset. There is no amount recorded as interest expense.

Payments associated with short-term leases are recognized as lease expenses on a straight-line basis over the period of the leases.

Subleases of right-of-use assets are accounted for similar to other leases. As an intermediate lessor, the Group separately accounts for the head-lease and sublease unless it is relieved of its primary obligation under the head-lease. Sublease income is recorded on a gross basis separate from the head-lease expenses. If the total remaining lease cost on the head-lease is more than the anticipated sublease income for the lease term, this is an indicator that the carrying amount of the right-of-use asset associated with the head-lease may not be recoverable, and the right-of-use asset will be assessed for impairment.

## 3. Cash and Cash Equivalents

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Cash at bank and on hand	71,860	78,556
Bank deposits maturing in three months or less (note (a))	11,500	7,480
	83,360	86,036
Denominated in:		
US\$ (note (b))	59,459	58,291
RMB (note (b))	19,443	23,254
UK Pound Sterling ("£") (note (b))	122	331
Hong Kong dollar ("HK\$")	4,336	4,160
	83,360	86,036

Notes:

(a) The weighted average effective interest rate on bank deposits for the six months ended June 30, 2019 and the year ended December 31, 2018 was 2.47% per annum and 1.98% per annum respectively (with maturity ranging from 5 to 35 days and 7 to 90 days respectively).

(b) Certain cash and bank balances denominated in RMB, US\$ and £ were deposited with banks in the PRC. The conversion of these balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

### 4. Short-term Investments

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Bank deposits maturing over three months (note)		
Denominated in:		
US\$	153,548	214,538
HK\$	380	377
	153,928	214,915

Note: The weighted average effective interest rate on bank deposits for the six months ended June 30, 2019 and the year ended December 31, 2018 was 2.77% per annum and 2.18% per annum respectively (with maturity ranging from 91 to 97 days and 91 to 100 days respectively).

### 5. Accounts Receivable—Third Parties

Accounts receivable from contracts with customers, net of allowance for doubtful accounts, consisted of the following:

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Accounts receivable, gross	42,779	40,217
Allowance for doubtful accounts	(21)	(41)
Accounts receivable, net	42,758	40,176

Substantially all accounts receivable are denominated in RMB, US\$ and HK\$ and are due within one year from the end of the reporting periods. The carrying values of accounts receivable approximate their fair values due to their short-term maturities.

Movements on the allowance for doubtful accounts:

2019	2018
(in US\$'(	000)
41	258
14	279
(34)	(235)
_	(1)
_	2
21	303
	(in US\$'( 41 14

#### 6. Inventories

Inventories, net of provision for excess and obsolete inventories, consisted of the following:

	June 30, 2019	December 31, 2018
	(in US	5'000)
Raw materials	1,865	652
Finished goods	12,358	11,657
	14,223	12,309

#### 7. Leases

The Group leases various offices, factories and other assets. Lease contracts are typically within a period of 1 to 5 years.

Leases consisted of the following:

	(in US\$'000)
Right-of-use assets	
Offices (note (a))	6,038
Factories	251
Others (note (b))	503
Total right-of-use assets	6,792
Lease liabilities—current	3,529
Lease liabilities—non-current	3,714
Total lease liabilities	7,243

Notes:

- (a) Includes (i) US\$0.2 million right-of-use asset for offices in the United States of America that is leased through July 2023 which includes an option to renew the lease up to an additional 3 years; and (ii) US\$1.2 million right-of-use asset for corporate offices in Hong Kong that is leased through May 2021 which includes a termination option with 3 months advance notice. The renewal and termination options were not recognized as part of the right-of-use assets and lease liabilities.
- (b) Includes US\$0.4 million right-of-use asset for retail space in the United Kingdom that is leased through May 2022 which the Group has subleased through May 2022.

Lease activities are summarized as follows:

	Six Months Ended June 30, 2019 (in US\$'000)
Lease expenses:	
Short-term leases with lease terms equal or less than 12 months	38
Leases with lease terms greater than 12 months	1,655
	1,693
Sublease rental income	61
Cash paid on lease liabilities	(1,782)
Non-cash: Lease liabilities recognized from obtaining right-of-use assets	2,453

The weighted average remaining lease term and the weighted average discount rate as at June 30, 2019 was 2.85 years and 4.20% respectively.

Future lease payments are as follows:

	June 30, 2019 (in US\$'000)
Lease payments:	(11 000 000)
Not later than 1 year	3,764
Between 1 to 2 years	1,973
Between 2 to 3 years	862
Between 3 to 4 years	650
Between 4 to 5 years	457
Total lease payments (note)	7,706
Less: Discount factor	(463)
Total lease liabilities	7,243

Note: Excludes future lease payments on lease not commenced as at June 30, 2019 in the aggregate amount of US\$0.9 million.

#### 8. Investments in Equity Investees

Investments in equity investees consisted of the following:

	2018	
(in US\$'000)		
59,695	60,992	
'8,593	68,812	
	(in US\$'000) 59,695 78,593	

Nutrition Science Partners Limited ("NSPL")	8,150	8,102
Other	539	412
	146,977	138,318

All of the equity investees are private companies and there are no quoted market prices available for their shares.

Summarized financial information for the significant equity investees HBYS, SHPL and NSPL is as follows:

### (i) Summarized balance sheets

	Commercial Platform			Innovation Platform		
		ner Health Prescription Drugs BYS SHPL		Drug NS		
	June 30, 2019	December 31, 2018	June 30, December 31, 2019 2018		June 30, 2019	December 31, 2018
			(in US	\$'000)		
Current assets	126,654	116,020	138,493	124,512	16,698	17,320
Non-current						
assets	98,552	100,353	97,568	98,532	_	
Current liabilities	(86,064)	(73,974)	(77,644)	(84,357)	(398)	(1,117)
Non-current	· /	. ,				· · ·
liabilities	(16,874)	(17,302)	(7,077)	(6,909)	_	
Net assets	122,268	125,097	151,340	131,778	16,300	16,203
Non-controlling						
interests	(2,877)	(3,113)	_	—	_	
	119,391	121,984	151,340	131,778	16,300	16,203

#### (ii) Summarized statements of operations

		Commercial	Platform		Innovation	Platform
	Consumer Health HBYS Six Months Ended June 30,		Prescription Drugs SHPL Six Months Ended June 30,		Drug R&D NSPL <sup>(note(a))</sup> Six Months Ended June 30,	
	2019	2018	2019	2018	2019	2018
			(in US\$	<sup>;</sup> 000)		
Revenue	118,047	118,983	158,874	152,717		
Gross profit	64,527	59,155	114,687	108,802	_	
Interest income	81	37	289	407	134	43
Finance cost	(9)	(135)		—	—	
Profit/(loss) before taxation	14,272	14,306	49,534	45,942	97	(4,818)
Income tax expense (note (b))	(2,286)	(2,362)	(7,479)	(7,127)		_
Net income/(loss)	11,986	11,944	42,055	38,815	97	(4,818)
Non-controlling interests	223	39	—	—	—	_
Net income/(loss) attributable to the shareholders of equity investee	12,209	11,983	42,055	38,815	97	(4,818)

Notes:

- (a) NSPL did not have any activity for the six months ended June 30, 2019 and primarily incurred research and development expenses during the six months ended June 30, 2018.
- (b) The main entities within the HBYS and SHPL groups have been granted the High and New Technology Enterprise ("HNTE") status. Accordingly, the entities were eligible to use a preferential income tax rate of 15% for the six months ended June 30, 2019 and 2018.

For the six months ended June 30, 2019 and 2018, other immaterial equity investees had net income of approximately US\$255,000 and US\$120,000 respectively.

#### (iii) Reconciliation of summarized financial information

Reconciliation of the summarized financial information presented to the carrying amount of investments in equity investees is as follows:

		Commercia	l Platform		Innova Platforn	
		Consumer Health         Prescription Drugs           HBYS         SHPL				&D L
	2019	2018	2019	2018	2019	2018
			(in US\$	'000)		
Opening net assets after non- controlling interests as at						
January 1	121,984	110,616	131,778	132,731	16,203	38,401
Impact of change in accounting policy (ASC 842)	(19)	_	(2)	_	_	_
Net income/(loss) attributable to the shareholders of equity						
investee	12,209	11,983	42,055	38,815	97	(4,818)
Dividends declared	(14,615)	—	(21,731)	(31,538)		—
Other comprehensive (loss)/income	(168)	1,693	(760)	2,339		
Investments						16,000
Closing net assets after non- controlling interests as at						
June 30	119,391	124,292	151,340	142,347	16,300	49,583
Group's share of net assets	59,695	62,146	75,670	71,173	8,150	24,792
Goodwill	· —	,	2,923	3,103		·
Carrying amount of investments as at June 30	59,695	62,146	78,593	74,276	8,150	24,792

Note: The Innovation Platform includes other immaterial equity investees. As at June 30, 2019 and December 31, 2018, the aggregate carrying amount of investments in NSPL and other immaterial equity investees was approximately US\$8,689,000 and US\$8,514,000 respectively.

The equity investees had the following capital commitments:

	June 30, 2019
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	1,750

# 9. Accounts Payable

	June 30, 2019	December 31, 2018
	(in US\$	·'000)
Accounts payable—third parties	19,217	14,158
Accounts payable—non-controlling shareholders of subsidiaries	4,132	
(Note 17(iv))		4,960
Accounts payable—related party (Note 17(ii))	2,796	6,507
	26,145	25,625

Substantially all accounts payable are denominated in RMB and US\$ and due within one year from the end of the reporting period. The carrying values of accounts payable approximate their fair values due to their short-term maturities.

# 10. Other Payables, Accruals and Advance Receipts

Other payables, accruals and advance receipts consisted of the following:

	June 30, 2019	December 31, 2018
	(in US\$	j'000)
Accrued salaries and benefits	9,602	8,715
Accrued research and development expenses	42,960	28,883
Accrued selling and marketing expenses	4,530	4,675
Accrued administrative and other general expenses	7,751	6,181

Deferred government incentives	505	1,817
Deposits	1,296	1,230
Dividend payable to a non-controlling shareholder of a subsidiary		
(Note 17(iv))	—	1,282
Accrued issuance costs	6,542	
Others	2,381	3,544
	75,567	56,327

#### 11. Bank Borrowings

Bank borrowings consisted of the following:

	June 30, 2019	December 31, 2018
	(in US	S\$'000)
Non-current		26,739

The weighted average interest rate for outstanding bank borrowings for the six months ended June 30, 2019 and the year ended December 31, 2018 was 3.29% per annum and 2.79% per annum respectively. The carrying amounts of the Group's bank borrowings were denominated in HK\$. The Group had fully repaid the bank borrowings in June 2019 and there were no outstanding bank borrowings as at June 30, 2019.

#### (i) 3-year term loan and 18-month revolving loan facilities

In November 2017, the Group through its subsidiary, entered into facility agreements with a bank for the provision of unsecured credit facilities in the aggregate amount of HK\$400,000,000 (US\$51,282,000). The credit facilities included (i) a HK\$210,000,000 (US\$26,923,000) 3-year term loan facility and (ii) a HK\$190,000,000 (US\$24,359,000) 18-month revolving loan facility. The term loan bore interest at 1.50% over the Hong Kong Interbank Offered Rate ("HIBOR") per annum and an upfront fee of HK\$1,575,000 (US\$202,000). The revolving loan facility bore interest at 1.25% over HIBOR per annum. The term loan was drawn in May 2018 and was fully repaid in June 2019. The revolving loan facility expired in May 2019.

#### (ii) 2-year revolving loan facilities

In August 2018, the Group through its subsidiary, entered into two separate facility agreements with banks for the provision of unsecured credit facilities in the aggregate amount of HK\$507,000,000 (US\$65,000,000). The first credit facility is a HK\$351,000,000 (US\$45,000,000) revolving loan facility, with a term of 2 years and an annual interest rate of 1.35% over HIBOR. The second credit facility is a HK\$156,000,000 (US\$20,000,000) revolving loan facility, with a term of 2 years and an annual interest rate of 1.35% over HIBOR. The second credit facility is a HK\$156,000,000 (US\$20,000,000) revolving loan facility, with a term of 2 years and an annual interest rate of 1.35% over HIBOR. These credit facilities are guaranteed by the Company. As at June 30, 2019 and December 31, 2018, no amount has been drawn from either of the revolving loan facilities.

In February 2017, the Group through its subsidiary, entered into two separate facility agreements with the banks for the provision of unsecured credit facilities in the aggregate amount of HK\$546,000,000 (US\$70,000,000). The first credit facility included (i) a HK\$156,000,000 (US\$20,000,000) term loan facility and (ii) a HK\$195,000,000 (US\$25,000,000) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The second credit facility included (i) a HK\$78,000,000 (US\$10,000,000) term loan facility and (ii) a HK\$117,000,000 (US\$15,000,000) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The term loans from the first and second credit facilities were repaid in May 2018. Both revolving loan facilities were terminated in August 2018.

# (iii) 3-year revolving loan facility and 3-year term loan and revolving loan facilities

In November 2018, the Group through its subsidiary renewed a 3-year revolving loan facility with a bank in the aggregate amount of HK\$234,000,000 (US\$30,000,000) with an annual interest rate of 0.85% over HIBOR. This credit facility is guaranteed by the Company. As at June 30, 2019 and December 31, 2018, no amount has been drawn from the revolving loan facility.

In May 2019, the Group through its subsidiary, entered into a separate facility agreement with the bank for the provision of additional unsecured credit facilities in the aggregate amount of HK\$400,000,000 (US\$51,282,000). The 3-year credit facilities include (i) a HK\$210,000,000 (US\$26,923,000) term loan facility and (ii) a HK\$190,000,000 (US\$24,359,000) revolving loan facility, both with an annual interest rate of 0.85% over HIBOR, and an upfront fee of HK\$819,000 (US\$105,000) on the term loan. These credit facilities are

guaranteed by the Company. As at June 30, 2019, no amount has been drawn from either of these credit facilities.

The Group's bank borrowings are repayable as from the dates indicated as follows:

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Not later than 1 year	_	_
Between 1 to 2 years	_	26,923
		26,923

As at June 30, 2019 and December 31, 2018, the Group had unutilized bank borrowing facilities of HK\$1,141,000,000 (US\$146,282,000) and HK\$931,000,000 (US\$119,359,000) respectively.

#### **12. Commitments and Contingencies**

#### **Capital commitments**

The Group had the following capital commitments:

	June 30, 2019
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	3,679

The Group does not have any other significant commitments or contingencies.

#### 13. Ordinary Shares

Pursuant to a resolution passed in the Annual General Meeting on April 24, 2019, the Company's authorized share capital was increased from US\$75,000,000 to US\$150,000,000 by the addition of 75,000,000 ordinary shares of US\$1.00 each (equivalent to 750,000,000 ordinary shares of US\$0.10 each after the share split effective on May 30, 2019) in the share capital of the Company.

Pursuant to a resolution passed in the Extraordinary General Meeting on May 29, 2019, with effect from May 30, 2019, each ordinary share of the Company was subdivided into 10 ordinary shares and the par value per ordinary share was changed from US\$1.00 to US\$0.10. All Company ordinary share and per share amounts presented were adjusted retroactively as the share split was effective when the interim unaudited condensed consolidated financial statements were issued.

As at June 30, 2019, the Company is authorized to issue 1,500,000,000 ordinary shares.

A summary of ordinary share transactions (in thousands) is as follows:

	2019	2018
As at January 1	666,577	664,470
Share option exercises		856
As at June 30	666,577	665,326

Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors of the Company.

## 14. Share-based Compensation

#### (i) Share-based Compensation of the Company

The Company conditionally adopted a share option scheme on June 4, 2005 (as amended on March 21, 2007) and such scheme has a term of 10 years. It expired in 2016 and no further share options can be granted. Another share option scheme was conditionally adopted on April 24, 2015 (the "HCML Share Option Scheme"). Pursuant to the HCML Share Option Scheme, the Board of Directors of the Company may, at its discretion, offer any employees and directors (including Executive and Non-executive Directors but excluding Independent Non-executive Directors) of the Company, holding companies of the Company and any of their subsidiaries or affiliates, and subsidiaries or affiliates of the Company share options to subscribe for shares of the Company.

As at June 30, 2019, the aggregate number of shares issuable under the HCML Share Option Scheme is 23,130,970 ordinary shares and the aggregate number of shares issuable under the prior share option scheme which expired in 2016 is 1,845,180 ordinary shares. Additionally, the number of shares authorized but unissued was 833,422,550 ordinary shares.

Share options granted are generally subject to a four-year vesting schedule, depending on the nature and the purpose of the grant. Share options subject to the four-year vesting schedule, in general, vest 25% upon the first anniversary of the vesting commencement date as defined in the grant letter, and 25% every subsequent year. However, certain share option grants may have a different vesting schedule as approved by the Board of Directors of the Company. No outstanding share options will be exercisable or subject to vesting after the expiry of a maximum of eight to ten years from the date of grant.

	Number of share options	Weighted average exercise price in £ per share	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in £'000)
Outstanding at January 1, 2018	11,264,120	1.77	6.29	43,158
Granted	10,606,260	4.69		
Exercised	(2,107,080)	1.40		
Cancelled	(1,208,450)	4.30		
Outstanding at December 31, 2018	18,554,850	3.31	7.35	15,158
Granted	180,000	4.22		
Cancelled	(648,090)	4.65		
Expired	(59,850)	4.65		
Outstanding at June 30, 2019	18,026,910	3.28	6.79	15,817
Vested and exercisable at December 31, 2018	8,032,040	1.68	4.84	14,843
Vested and exercisable at June 30, 2019	10,270,760	2.29	5.29	15,570

A summary of the Company's share option activity and related information is as follows:

In estimating the fair value of share options granted, the following assumptions were used in the Polynomial model for awards granted in the periods indicated:

		Year End	led Decemb	oer 31,		Six Months Ended June 30,
	2011	2013	2016	2017	2018	2019
Weighted average grant date fair value of share						
options (in £ per share)	0.18	0.32	0.90	1.27	1.67	1.51
Significant inputs into the valuation model (weighted average):						
Exercise price (in £ per share)	0.44	0.61	1.97	3.11	4.69	4.22
Share price at effective date of grant (in £ per share)	0.43	0.61	1.97	3.11	4.66	4.22
Expected volatility (note (a))	46.6%	36.0%	39.0%	36.3%	37.6%	37.7%
Risk-free interest rate (note (b))	3.13%	3.16%	1.00%	1.17%	1.46%	1.08%
Contractual life of share options (in years)	10	10	8	10	10	10
Expected dividend yield (note (c))	0%	0%	0%	0%	0%	0%

Notes:

- (a) The Company calculated its expected volatility with reference to the historical volatility prior to the issuances of share options.
- (b) The risk-free interest rates used in the Polynomial model are with reference to the sovereign yield of the United Kingdom because the Company's ordinary shares are currently listed on AIM and denominated in £.
- (c) The Company has not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore uses an expected dividend yield of zero in the Polynomial model.

The Company will issue new shares to satisfy share option exercises. The following table summarizes the Company's share option exercises:

	Six Month June	
	2019	2018
	(in US	\$'000)
Cash received from share options exercised	—	720
Total intrinsic value of share options exercised	—	4,817

The Group recognizes compensation expense on a graded vesting approach over the requisite service period. The following table presents share-based compensation expense included in the Group's condensed consolidated statements of operations:

		Six Months Ended June 30,	
	2019	2018	
	(in US	(in US\$'000)	
Research and development expenses	3,756	2,616	
Administrative expenses	371	175	
	4,127	2,791	

As at June 30, 2019, the total unrecognized compensation cost was US\$10,391,000, and will be recognized on a graded vesting approach over the weighted average remaining service period of 2.86 years.

#### (ii) LTIP

The Company grants awards under the LTIP to participating directors and employees, giving them a conditional right to receive ordinary shares of the Company or the equivalent ADS (collectively the "Awarded Shares") to be purchased by the Trustee up to a cash amount. Vesting will depend upon continued employment of the award holder with the Group and will otherwise be at the discretion of the Board of Directors of the Company. Additionally, some awards are subject to change based on annual performance targets prior to their determination date.

#### LTIP awards prior to the determination date

Performance targets vary by award, and may include targets for shareholder returns, free cash flows, revenues, net profit after taxes and the achievement of clinical and regulatory milestones. As the extent of achievement of the performance targets is uncertain prior to the determination date, a probability based on management's assessment on the achievement of the performance target has been assigned to calculate the amount to be recognized as an expense over the requisite period with a corresponding entry to liability.

#### LTIP awards after the determination date

Upon the determination date, the Company will pay a determined monetary amount, up to the maximum cash amount based on the actual achievement of the performance target specified in the award, to the Trustee to purchase the Awarded Shares. Any cumulative compensation expense previously recognized as a liability will be transferred to additional paid-in capital, as an equity-settled award. If the performance target is not achieved, no Awarded Shares of the Company will be purchased and the amount previously recorded in the liability will be reversed through share-based compensation expense.

#### Granted awards under the LTIP are as follows:

Grant date	Maximum cash amount per annum (in US\$ millions)	Covered financial years	Performance target determination date
October 19, 2015	1.8	2014-2016	note (a)
March 24, 2016	0.3	note (b)	note (b)
March 15, 2017	0.4	note (c)	note (c)
March 15, 2017 and August 2, 2017	6.0	2017-2019	note (d)
December 15, 2017	0.5	2018-2019	note (d)
August 6, 2018	0.1	2018-2019	note (d)
December 14, 2018	1.5	2019	note (d)

#### Notes:

- (a) The annual performance target determination date is the date of the announcement of the Group's annual results for the covered financial year and vesting occurs one business day after the publication date of the annual report of the Company for the financial year falling two years after the covered financial year to which the LTIP award relates.
- (b) This award does not stipulate performance targets and is subject to a vesting schedule of 25% on each of the first, second, third and fourth anniversaries of the date of grant.
- (c) This award did not stipulate performance targets and vested one business day after the publication date of the annual report for the 2017 financial year.
- (d) The annual performance target determination date is the date of the announcement of the Group's annual results for the covered financial year and vesting occurs two business days after the announcement of the Group's annual results for the financial year falling two years after the covered financial year to which the LTIP award relates.

The Trustee has been set up solely for the purpose of purchasing and holding the Awarded Shares during the vesting period on behalf of the Group using funds provided by the Group. On the determination date, if any, the Company will determine the cash amount, based on the actual achievement of each annual performance target, for the Trustee to purchase the Awarded Shares. The Awarded Shares will then be held by the Trustee until they are vested.

The Trustee's assets include treasury shares and funds for additional treasury shares, trustee fees and expenses. The number of treasury shares (in the form of ordinary shares or ADS of the Company) purchased and held by the Trustee were as follows:

	Number of treasury shares	Cost (in US\$'000)
As at January 1, 2018	559,775	1,957
Purchased	795,005	5,451
Vested	(233,750)	(731)
As at December 31, 2018	1,121,030	6,677
Purchased	60,430	346
Vested	(240,150)	(944)
As at June 30, 2019	941,310	6,079

For the six months ended June 30, 2019 and 2018, US\$254,000 and US\$93,000 of the LTIP awards were forfeited respectively.

The following table presents the share-based compensation expenses recognized under the LTIP awards:

	Six Months Ended	Six Months Ended June 30,		
	2019	2018		
	(in US\$'000	)		
Research and development expenses	543	878		
Selling and administrative expenses	827	723		
	1,370	1,601		
Recorded with a corresponding credit to:				
Liability	590	789		
Additional paid-in capital	780	812		
	1,370	1,601		

For the six months ended June 30, 2019 and 2018, US\$526,000 and US\$1,770,000 were reclassified from liability to additional paid-in capital respectively upon LTIP awards reaching the determination date. As at June 30, 2019 and December 31, 2018, US\$1,299,000 and US\$1,235,000 were recorded as liabilities respectively for LTIP awards prior to the determination date.

As at June 30, 2019, the total unrecognized compensation cost was approximately US\$3,624,000, which considers expected performance targets and the amount expected to vest, and will be recognized over the requisite periods.

# 15. Revenues

The following table presents disaggregated revenue:

	Six	Six Months Ended June 30, 2019		
	Innovation Platform	Commercial Platform	Total	
		(in US\$'000)		
Goods—Manufacturing	2,994	—	2,994	
Goods—Distribution	—	87,596	87,596	
Services	7,308	2,584	9,892	
Royalties	1,715	—	1,715	
	12,017	90,180	102,197	
Third parties	11,765	86,448	98,213	
Related parties (Note 17(i))	252	3,732	3,984	
	12,017	90,180	102,197	

	Six	Six Months Ended June 30, 2018		
	Innovation Platform	Commercial Platform	Total	
		(in US\$'000)		
Goods—Distribution	—	82,912	82,912	
Services	13,624	5,653	19,277	
	13,624	88,565	102,189	
Third parties	8,548	85,116	93,664	
Related parties (Note 17(i))	5,076	3,449	8,525	
	13,624	88,565	102,189	

#### 16. Research and Development Expenses

Research and development expenses are summarized as follows:

	Six Months Ended June 30,	
	2019	2018
	(in US\$'000)	
Clinical trial related costs	43,707	40,244
Personnel compensation and related costs	21,917	17,282
Other research and development expenses	3,663	2,527
	69,287	60,053

# 17. Significant Transactions with Related Parties and Non-Controlling Shareholders of Subsidiaries

The Group has the following significant transactions with related parties and non-controlling shareholders of subsidiaries, which were carried out in the normal course of business at terms determined and agreed by the relevant parties.

### (i) Transactions with related parties:

	Six Months End	Six Months Ended June 30,	
	2019	2018	
	(in US\$'(	)00)	
Sales to:			
Indirect subsidiaries of CK Hutchison	3,732	3,449	
Revenue from research and development services from:			
Equity investees	252	5,076	
Purchases from:			
Equity investees	1,222	1,197	
Rendering of marketing services from:			
Indirect subsidiaries of CK Hutchison	198	256	
An equity investee	2,682	6,561	
	2,880	6,817	
Rendering of support services from:			

An indirect subsidiary of CK Hutchison

# (ii) Balances with related parties included in:

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Accounts receivable—related parties		
Indirect subsidiaries of CK Hutchison (note (a))	1,794	2,709
An equity investee (note (a))		73
	1,794	2,782
Accounts payable		
An equity investee (note (a))	2,796	6,507
Amounts due from related parties		
Equity investees (note (a))	894	889
Amounts due to related parties		
An indirect subsidiary of CK Hutchison (note (b))	290	432
Other deferred income		
An equity investee (note (c))	1,245	1,356

465

455

Notes:

- (a) Balances with related parties are unsecured, repayable on demand and interest-free. The carrying values of balances with related parties approximate their fair values due to their short-term maturities.
- (b) Amounts due to an indirect subsidiary of CK Hutchison are unsecured, repayable on demand and interest-bearing if not settled within one month.
- (c) Other deferred income represents amounts recognized from granting of promotion and marketing rights.

# (iii) Transactions with non-controlling shareholders of subsidiaries:

	Six Months En	Six Months Ended June 30,	
	2019	2018	
	(in US\$	o'000)	
Sales	12,146	10,506	
Purchases	6,397	8,113	
Interest expense		39	
Dividend paid	1,282		

# (iv) Balances with non-controlling shareholders of subsidiaries included in:

	June 30, 2019	December 31, 2018
	(in US	\$'000)
Accounts receivable—third parties	5,631	5,070
Accounts payable	4,132	4,960
Other payables, accruals and advance receipts		
Dividend payable		1,282
Other non-current liabilities		
Loan	579	579

# 18. Income Taxes

	Six Months End	Six Months Ended June 30,	
	2019	2018	
	(in US\$'	000)	
Current tax			
HK (note (a))	220	289	
PRC (note (b))	822	1,010	
U.S. (note (c))	347	104	
Deferred income tax	1,073	1,277	
Income tax expense	2,462	2,680	

#### Notes:

- (a) The Company, two subsidiaries incorporated in the British Virgin Islands and its Hong Kong subsidiaries are subject to Hong Kong profits tax which has been provided for at the rate of 16.5% on the estimated assessable profits less estimated available tax losses in each entity.
- (b) Taxation in the PRC has been provided for at the applicable rate on the estimated assessable profits less estimated available tax losses, if any, in each entity. Under the PRC Enterprise Income Tax Law (the "EIT Law"), the standard enterprise income tax rate is 25%. In addition, the EIT Law provides for, among others, a preferential tax rate of 15% for companies which qualify as HNTE. Hutchison MediPharma Limited and its wholly-owned subsidiary Hutchison MediPharma (Suzhou) Limited qualify as a HNTE up to December 31, 2019 and 2020 respectively.

Pursuant to the EIT law, a 10% withholding tax is levied on dividends paid by PRC companies to their foreign investors. A lower withholding tax rate of 5% is applicable under the China-HK Tax Arrangement if direct foreign investors with at least 25% equity interest in the PRC companies are Hong Kong tax residents, and meet the conditions or requirements pursuant to the relevant PRC tax regulations regarding beneficial ownership. Since the equity holders of the major subsidiaries and equity investees of the Company are Hong Kong incorporated companies and Hong Kong tax residents, and meet the aforesaid conditions or requirements, the Company has used 5% to provide for deferred tax liabilities on retained earnings which are anticipated to be distributed. As at June 30, 2019 and December 31, 2018, the amounts accrued in deferred tax liabilities relating to withholding tax on dividends were determined on the basis that 100% of the distributable reserves of the major subsidiaries and equity investees operating in the PRC will be distributed as dividends.

(c) The Company's subsidiary in the U.S. with operations in New York State is subject to U.S. federal and state taxes, and have been provided for at approximately 21% and 9% on the estimated assessable profit respectively. Certain income receivable by the Company is subject to U.S. withholding tax of 30%.

The reconciliation of the Group's reported income tax expense to the theoretical tax amount that would arise using the tax rates of the Company against the Group's loss before income taxes and equity in earnings of equity investees is as follows:

	Six Months Ended June 30,		
	2019	2018	
	(in US\$'00	)0)	
Loss before income taxes and equity in earnings of equity investees	(68,301)	(50,495)	
Tax calculated at the statutory tax rate of the Company	(11,270)	(8,332)	
Tax effects of:			
Different tax rates available in different jurisdictions	1,351	893	
Tax valuation allowance	13,309	10,231	
Preferential tax deduction	(2,908)	(1,763)	
Expenses not deductible for tax purposes	1,094	690	
Utilization of previously unrecognized tax losses	(49)	(2)	
Withholding tax on undistributed earnings of PRC entities	1,386	1,323	
Others	(451)	(360)	
Income tax expense	2,462	2,680	

#### 19. Losses per Share

# (i) Basic losses per share

Basic losses per share is calculated by dividing the net loss attributable to the Company by the weighted average number of outstanding ordinary shares in issue during the period. Treasury shares held by the Trustee are excluded from the weighted average number of outstanding ordinary shares in issue for purposes of calculating basic losses per share.

	Six Months Ended June 30,		
	2019 2018		
Weighted average number of outstanding ordinary shares in issue	665,553,637	663,894,540	
Net loss attributable to the Company (US\$'000)	(45,369)	(32,691)	
Losses per share attributable to the Company (US\$ per share)	(0.07)	(0.05)	

#### (ii) Diluted losses per share

Diluted losses per share is calculated by dividing net loss attributable to the Company by the weighted average number of outstanding ordinary shares in issue and dilutive ordinary share equivalents outstanding during the period. Dilutive ordinary share equivalents include shares issuable upon the exercise or settlement of share option and LTIP awards issued by the Company using the treasury stock method.

For the six months ended June 30, 2019 and 2018, the share options and LTIP awards issued by the Company were not included in the calculation of diluted losses per share because of their anti-dilutive effect. Therefore, diluted losses per share was equal to basic losses per share for the six months ended June 30, 2019 and 2018.

Note: The losses per share attributable to the Company—basic and diluted presented were adjusted retroactively for each of the six months ended June 30, 2019 and 2018 to take into account the share split approved by ordinary resolution at the Extraordinary General Meeting of the Company held on May 29, 2019, pursuant to which each ordinary share was subdivided into 10 ordinary shares with effect from May 30, 2019.

### 20. Segment Reporting

The Group determines its operating segments from both business and geographic perspectives as follows:

- Innovation Platform (Drug R&D): focuses on discovering, developing and commercializing targeted therapeutics in oncology and autoimmune diseases, and the provision of research and development services; and
- (ii) Commercial Platform: comprises of the manufacture, marketing and distribution of prescription and over-the-counter pharmaceuticals in the PRC as well as consumer health products through Hong Kong. The Commercial Platform is further segregated into two core business areas:
  - (a) Prescription Drugs: comprises the development, manufacture, distribution, marketing and sale of prescription pharmaceuticals; and
  - (b) Consumer Health: comprises the development, manufacture, distribution, marketing and sale of over-the-counter pharmaceuticals and consumer health products.

Innovation Platform and Prescription Drugs businesses under the Commercial Platform are primarily located in the PRC. The locations for Consumer Health business under the Commercial Platform are further segregated into the PRC and Hong Kong.

The performance of the reportable segments is assessed based on three measurements: (a) losses or earnings of subsidiaries before interest income, interest expense, income tax expenses and equity in earnings of equity investees, net of tax ("Adjusted (LBIT)/EBIT" or "Adjusted LBIT"), (b) equity in earnings of equity investees, net of tax and (c) operating (loss)/profit.

The segment information is as follows:

	Six Months Ended June 30, 2019						
	Innovation Platform		Commercia	l Platform			
	Drug R&D	Prescription Drugs	Consum	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Revenue from external							
customers	12,017	72,618	6,192	11,370	90,180	—	102,197
Adjusted (LBIT)/EBIT	(64,231)	2,191	464	971	3,626	(10,069)	(70,674)
Interest income	205	30	16	2	48	2,808	3,061
Equity in earnings of equity							
investees, net of tax	176	21,027	6,105		27,132		27,308
Operating (loss)/profit	(63,850)	23,248	6,585	973	30,806	(7,261)	(40,305)
Interest expense		—			—	688	688
Income tax expense	120	624	138	142	904	1,438	2,462

Net (loss)/income attributable to the							
Company	(63,813)	21,815	5,542	385	27,742	(9,298)	(45,369)
Depreciation/amortization	2,191	80	11	45	136	78	2,405
Additions to non-current assets (other than financial instruments	2 200	2 624	0	0	0.626	7	5.042
and deferred tax assets)	3,300	2,624	9	3	2,636		5,943

	As at June 30, 2019						
	Innovation Platform		Commercia	al Platform		_	
	Drug R&D	Prescription Drugs	Consum	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Total assets	97,488	134,002	65,790	11,626	211,418	186,308	495,214
Property, plant and							
equipment	16,317	347	69	345	761	591	17,669
Right-of-use assets	2,753	2,381	34	463	2,878	1,161	6,792
Leasehold land	1,157	—	_	—			1,157
Goodwill		2,779	407		3,186		3,186
Other intangible asset	—	315	_	_	315	_	315
Investments in equity	8,689	78,593	59,695		138,288		146,977
investees							

	Six Months Ended June 30, 2018						
	Innovation Platform	<b>D</b> econstruction	Commerci	ial Platform		-	
	Drug R&D	Prescription Drugs	Consum	ner Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Revenue from external							
customers	13,624	67,950	6,559		88,565		102,189
Adjusted (LBIT)/EBIT	(50,718)	3,457	456		5,497	(7,619)	(52,840)
Interest income	26	23	7	32	62	2,701	2,789
Equity in earnings of equity							
investees, net of tax	(2,349)	19,408	5,991		25,399		23,050
Operating (loss)/profit	(53,041)	22,888	6,454	1,616	30,958	(4,918)	(27,001)
Interest expense	—			39	39	405	444
Income tax expense	20	813	124	264	1,201	1,459	2,680
Net (loss)/income							
attributable to the							
Company	(52,930)	20,768	5,497	649	26,914	(6,675)	(32,691)
Depreciation/amortization	1,584	68	12	10	90	14	1,688
Additions to non-current							
assets (other than							
financial instruments							
and deferred tax assets)	1,564	5	7	14	26	5	1,595
-			As at D	December 31, 2	018		
	Innovation Platform		Commercia	Diatform			
-		Prescription	Commercia	rtationin			
	Drug R&D	Drugs	Consume	r Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Total assets	100,388	118,445	67,352	11,686	197,483	234,247	532,118
Property, plant and							
equipment	15,223	204	71	418	693	700	16,616
Leasehold land	1,174						1,174
Goodwill	_	2,779	407	_	3,186		3,186
Other intangible asset	_	347	—	_	347		347
Investments in equity							
investees	8,514	68,812	60,992		129,804		138,318

Revenue from external customers is after elimination of inter-segment sales. Sales between segments are carried out at mutually agreed terms.

There was one customer which accounted for over 10% of the Group's revenue for the six months ended June 30, 2019 and 2018 respectively.

Unallocated expenses mainly represent corporate expenses which include corporate employee benefit expenses and the relevant share-based compensation expenses. Unallocated assets mainly comprise cash and cash equivalents and short-term investments.

A reconciliation of Adjusted LBIT to net loss is as follows:

		Six Months Ended June 30,		
	2019	2018		
	(in US	\$'000)		
Adjusted LBIT	(70,674)	(52,840)		
Interest income	3,061	2,789		
Equity in earnings of equity investees, net of tax	27,308	23,050		
Interest expense	(688)	(444)		
Income tax expense	(2,462)	(2,680)		
Net loss	(43,455)	(30,125)		

# 21. Note to Condensed Consolidated Statements of Cash Flows

Reconciliation of net loss for the period to net cash used in operating activities:

	Six Months Ended June 30,		
	2019	2018	
	(in US\$'0	00)	
Net loss	(43,455)	(30,125)	
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	2,405	1,688	
Share-based compensation expense—share options	4,127	2,791	
Share-based compensation expense—LTIP	1,370	1,601	
Equity in earnings of equity investees, net of tax	(27,308)	(23,050)	
Dividends received from equity investees	18,173	23,526	
Changes in right-of-use assets	(929)		
Other adjustments	1,107	990	
Changes in working capital			
Accounts receivable—third parties	(2,562)	(6,053)	
Inventories	(2,113)	2,041	
Accounts payable	520	(5,057)	
Other payables, accruals and advance receipts	14,606	10,215	
Lease liabilities	764	—	
Other changes in working capital	3,250	2,837	
Total changes in working capital	14,465	3,983	
Net cash used in operating activities	(30,045)	(18,596)	

# 22. Litigation

From time to time, the Group may become involved in litigation relating to claims arising from the ordinary course of business. The Group believes that there are currently no claims or actions pending against the Group, the ultimate disposition of which could have a material adverse effect on the Group's results of operations, financial position or cash flows. However, litigation is subject to inherent uncertainties and the Group's view of these matters may change in the future. When an unfavorable outcome occurs, there exists the possibility of a material adverse impact on the Group's financial position and results of operations for the periods in which the unfavorable outcome occurs, and potentially in future periods.

On May 17, 2019, Luye Pharma Hong Kong Ltd. issued a notice to the Group purporting to terminate a distribution agreement that granted the Group exclusive commercial rights to Seroquel in the PRC for failure to meet a pre-specified target. The Group disagrees with this assertion and believes that they have no basis for termination, and therefore intends to enforce its rights under the current agreement. On July 29, 2019, the Group

initiated arbitration in Hong Kong. Accordingly, no adjustment has been made to Seroquel-related balances as at June 30, 2019, including accounts receivable, inventories, long-term prepayment and accounts payable of US\$1.1 million, US\$0.1 million, US\$1.2 million and US\$2.2 million respectively.

### 23. Subsequent Events

The Group evaluated subsequent events through July 30, 2019, which is the date when the interim unaudited condensed consolidated financial statements were issued.