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HUTCHMED (China) Limited

和黃醫藥（中國）有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 13)

HUTCHMED Reports 2023 Interim Results and Provides Business Updates

Strong execution on strategic direction, delivering near-term value while charting a path for growth, exemplified by global partnership with Takeda

Revenue grew 164% (173% CER) to US\$533 million, with net income to HUTCHMED of US\$169 million (which include US\$259 million of the upfront recognized from Takeda)

Company to Host Interim Results Call & Webcast Today at 8 p.m. HKT / 1 p.m. BST / 8 a.m. EDT

Company to host a Capital Markets Day in Q4 this year

HUTCHMED (China) Limited ("[HUTCHMED](#)", the "Company" or "we"), the innovative, commercial-stage biopharmaceutical company, today reports its unaudited financial results for the six months ended June 30, 2023 and provides updates on key clinical and commercial developments.

All amounts are expressed in U.S. dollars unless otherwise stated.

Strategic: clinical, financial, and regulatory progress demonstrates strong delivery on the strategy

- Focusing on driving near-term value creation and establishing a self-sustaining business over the long term, with the goal of bringing innovative medicines to patients around the world.
- Significant progress towards bringing medicines to patients outside China through global partnerships: closed fruquintinib license agreement with Takeda¹ in March, which can potentially bring in up to \$1.13 billion in payments including \$400 million upfront payment received, plus royalties on net sales.

Product & pipeline: fruquintinib advancing to global launches, with continued progress across portfolio

- NDA² for fruquintinib granted priority review by the U.S. FDA³, with a PDUFA⁴ goal date of November 30, 2023. Takeda preparing for fruquintinib launches worldwide with MAA⁵ validated by the EMA⁶ in June and the Japan NDA submission planned this year. Global regulatory filings supported by results from FRESCO-2, recently published in *The Lancet*, and data from FRESCO.
- Fruquintinib NDA for second-line gastric cancer accepted in China, where fruquintinib is available and reimbursed under the brand name ELUNATE[®] for the treatment of metastatic CRC⁷; Breakthrough Therapy Designation in endometrial cancer.
- All three HUTCHMED medicines marketed in China now included in the NRDL⁸.
- Registration study readouts expected in the second half for two potential new medicines in China, soveplepib and amdizalisib. New registration studies initiated for savolitinib in gastric cancer and HMPL-453 for IHCC⁹; over 15 registration studies ongoing, across seven drug candidates.
- Productive discovery research continues, with another novel drug candidate in clinical development (SHP2¹⁰ inhibitor HMPL-415).

Financial: HUTCHMED remains on track to become self-sustaining in 2025

- Total revenues up 164% (173% at CER¹¹) to \$532.9 million for the first half of 2023, with Oncology/Immunology consolidated revenues up 294% (301% at CER) to \$359.2 million.
- Strategy has allowed HUTCHMED to conserve cash and significantly reduce costs, with a substantial **cash balance of \$856.2 million** on June 30, 2023 including \$400 million received from Takeda.
- \$258.7 million of the Takeda upfront payment recognized as revenue in the first half of 2023, resulting in net income of \$168.6 million; we expect to recognize approximately \$280 million of this payment for the full year.
- R&D¹² expenses decreased primarily due to our portfolio optimization efforts, while the reduction in SG&A expenses¹³ was mainly due to decreased administrative expenses after restructuring our U.S. operations.

2023 INTERIM RESULTS & BUSINESS UPDATES

Mr Simon To, Executive Chairman of HUTCHMED, said, “The first half of 2023 has been successful for HUTCHMED. In late 2022, we announced our pipeline prioritization plan and intention to seek global partners to bring our medicines to help patients outside of China. Six months later, this strategy is already delivering significant results to our operations. We are successfully navigating the current challenging capital markets, while making significant progress towards our goal of becoming a self-sustaining, truly global biopharma company. Crucially, it means that we are well positioned to reach more patients than ever with our medicines.”

“In March, we closed a licensing deal for fruquintinib with Takeda and we are confident that they have the commitment, expertise, and commercial infrastructure to successfully roll out this innovative medicine to patients across the globe. The FDA Priority Review PDUFA date for fruquintinib is now set for November 30 this year, reflecting its potential to deliver significant improvement over currently available treatments.”

Dr Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, said, “With the sharpening of our goals and priorities, we now have more resources to advance our assets and drive near-term value, and we are pleased to report on the important progress made so far this year. We have over 15 registration/registration-intent studies ongoing with seven drug candidates. Alongside this, our team has presented data at a number of leading medical conferences, including AACR¹⁴, ASCO¹⁵, ASCO GI¹⁶, EHA¹⁷ and ICML¹⁸, showcasing the productivity of our world class R&D engine. Furthermore, commercial performance has remained strong this year, with robust sales growth of our in-house developed oncology products in China. All three marketed medicines are now included on the NRDL, in line with our commitment to patient access. Moreover, our strategy means we are in a strong financial position as we look to continue developing our clinical programs. We started the second half of 2023 with \$856 million in cash resources, including the \$400 million received from Takeda.”

“HUTCHMED is now well placed for further successful product launches and life cycle extensions. In particular, we look forward to continuing the positive momentum with fruquintinib regulatory reviews around the world, and readouts from our registration studies for soveplenib and amdizalisib later this year. As the last six months have shown, HUTCHMED clearly has the right strategy, leadership team, and vision to become a truly global biopharma, and I am confident that HUTCHMED will continue to deliver on this potential.”

I. COMMERCIAL OPERATIONS

Total revenues increased 164% (173% at CER) to \$532.9 million in the first half of 2023 (H1-22: \$202.0m), driven by Oncology/Immunology partnering, its strong commercial progress in China, and growth in third-party distribution sales.

Oncology/Immunology consolidated revenues were up 294% (301% at CER) to \$359.2 million (H1-22: \$91.1m); driven by recognition of \$258.7 million in partnering revenue for the upfront payment from Takeda, and our strong product sales growth resulting from in-market sales¹⁹ up 16% (25% at CER) to \$101.3 million (H1-22: \$87.4m);

- ELUNATE[®] (fruquintinib) in-market sales in the first half of 2023 increased 12% (20% at CER) to \$56.3 million (H1-22: \$50.4m), reflecting its continued lead in market share;
- SULANDA[®] (surufatinib) in-market sales in the first half of 2023 increased 66% (79% at CER) to \$22.6 million (H1-22: \$13.6m), reflecting the build-up in patients on treatment over 18 months on the NRDL;
- ORPATHYS[®] (savolitinib) in-market sales in the first half of 2023 decreased 5% (increased 2% at CER) to \$22.0 million (H1-22: \$23.3m). Sales in the first quarter were impacted by customary channel fluctuations ahead of its NRDL inclusion

on March 1, subsequently followed by an increase in sales volume, with the second quarter of 2023 up 84% compared to the second quarter of 2022;

- R&D services income up 62% (66% at CER) to \$20.4 million (H1-22: \$12.6m), now also including fees from our new partner Takeda for the management of regulatory activities;
- Takeda upfront payment of \$400.0 million received, of which \$250.1 million (62%) attributable to the license was recognized immediately. The remaining balance will be recognized when ongoing services and performance obligations are completed. Up to June 2023, we have recognized an aggregate of \$258.7 million to revenue and expect around \$280 million by year end; and
- Successful management of commercial operations to expand coverage of oncology hospitals and physicians despite challenges of pandemic-related disruptions around the start of the year.

\$'millions	In-market Sales*			Consolidated Revenues**		
	H1 2023	H1 2022	%Δ (CER)	H1 2023	H1 2022	%Δ (CER)
	Unaudited			Unaudited		
ELUNATE®	\$56.3	\$50.4	+12% (+20%)	\$42.0	\$36.0	+16% (+25%)
SULANDA®	\$22.6	\$13.6	+66% (+79%)	\$22.6	\$13.6	+66% (+79%)
ORPATHYS®	\$22.0	\$23.3	-5% (+2%)	\$15.1	\$13.8	+10% (+17%)
TAZVERIK®	\$0.4	\$0.1	+560% (+583%)	\$0.4	\$0.1	+560% (+583%)
Products Sales	\$101.3	\$87.4	+16% (+25%)	\$80.1	\$63.5	+26% (+35%)
Other R&D services income				\$20.4	\$12.6	+62% (+66%)
Upfront and milestone income				\$258.7	\$15.0	
Total Oncology/Immunology				\$359.2	\$91.1	+294% (+301%)
Other Ventures				\$173.7	\$110.9	+57% (+67%)
Total revenues				\$532.9	\$202.0	+164% (+173%)

*= For ELUNATE® and ORPATHYS®, represents total sales to third parties as provided by Lilly²⁰ and AstraZeneca, respectively, and their sales to other third parties as invoiced by HUTCHMED.

**= For ELUNATE®, represents manufacturing fees, commercial service fees and royalties paid by Lilly, to HUTCHMED, and sales to other third parties invoiced by HUTCHMED; for ORPATHYS® represents manufacturing fees and royalties paid by AstraZeneca and sales to other third parties invoiced by HUTCHMED; for SULANDA® and TAZVERIK®, represents the Company's sales of the products to third parties.

II. REGULATORY UPDATES

China

- NDA accepted in China in second-line gastric cancer for fruquintinib in combination with paclitaxel in April 2023;
- Designated Breakthrough Therapy in China for fruquintinib in combination with sintilimab in July 2023 for the treatment of advanced endometrial cancer;
- Consulted with NMPA²¹ on the registration study plan of HMPL-453 for IHCC in March 2023;
- Consulted with NMPA on registration study plan of savolitinib for gastric cancer in March 2023; and
- Received Macau approvals for tazemetostat and savolitinib in March 2023.

Ex-China

- Fruquintinib submission to U.S. FDA accepted in May 2023 and granted Priority Review for previously treated metastatic CRC. The PDUFA goal date assigned by the FDA is November 30, 2023;
- Fruquintinib submission to the EMA was validated in June 2023;
- Fruquintinib submission to the Japanese PMDA²² expected to be completed in 2023;

- Savolitinib, in combination with TAGRISSO[®], designated a U.S. FDA Fast Track program in January 2023 for the treatment of patients with NSCLC²³ with MET²⁴ overexpression and/or amplification, and who have had disease progression during or following prior TAGRISSO[®]; and
- Following dialogue with the PMDA regarding surufatinib, we have decided not to file a Japanese NDA on the basis of the clinical trial data available.

III. CLINICAL DEVELOPMENT ACTIVITIES

Savolitinib (ORPATHYS[®] in China), a highly selective oral inhibitor of MET being developed broadly across MET-driven patient populations in lung, gastric and papillary renal cell carcinomas

- Aligned with FDA and enrolling the pivotal Phase II study SAVANNAH for potential accelerated approval of the TAGRISSO[®] combination for NSCLC MET patients following progression on TAGRISSO[®] (NCT03778229);
- Completed enrollment of the confirmatory China Phase IIIb study in MET exon 14 skipping alteration NSCLC in both first-line and second-line and above patients (NCT04923945);
- After consultation with NMPA, initiated the registration stage of a China Phase II study in second-line gastric cancer patients with MET amplification (NCT04923932); and
- Continued enrolling five other registration studies, including SAFFRON, the global, pivotal Phase III study of the TAGRISSO[®] combination supporting SAVANNAH (NCT05261399); SACHI, a pivotal Phase III study of the TAGRISSO[®] combination in China for NSCLC patients with MET amplification following progression on EGFR²⁵ inhibitor treatment (NCT05015608); SANOVO, a pivotal Phase III study of the TAGRISSO[®] combination in China in first-line NSCLC patients harboring EGFR mutation and MET overexpression (NCT05009836); and SAMETA, a global Phase III study in MET-driven PRCC²⁶ (NCT05043090).

Potential upcoming clinical and regulatory milestones for savolitinib:

- Complete enrollment of SAVANNAH pivotal Phase II study in 2023;
- Complete enrollment of SOUND, a China Phase II study of the IMFINZI[®] combination in EGFR wild-type NSCLC patients with MET alterations (NCT05374603) around year end 2023; and
- Complete recruitment of SACHI, a pivotal Phase III study of the TAGRISSO[®] combination in China for NSCLC patients with MET amplification following progression on EGFR inhibitor treatment (NCT05015608) in mid-2024.

Fruquintinib (ELUNATE[®] in China), a highly selective oral inhibitor of VEGFR²⁷ 1/2/3 designed to improve kinase selectivity to minimize off-target toxicity and thereby improve tolerability

- Completed recruitment of the endometrial cancer cohort of a China Phase II study of fruquintinib in combination with PD-1²⁸ inhibitor sintilimab in July 2023 for potential registration (NCT03903705);
- Published in peer-reviewed journal *The Lancet* positive results of the global Phase III FRESCO-2 registration trial (NCT04322539) in previously treated metastatic CRC patients in June 2023; and
- Updated results from the clear cell RCC²⁹ cohort of a China Phase II study of fruquintinib in combination with PD-1 inhibitor sintilimab at ASCO 2023, these results led to the Phase II/III trial (NCT05522231).

Potential upcoming clinical and regulatory milestones for fruquintinib:

- Complete NDA submission to the Japanese PMDA in 2023;
- Submit FRUTIGA results for presentation at a scientific conference (NCT03223376);
- Consult with NMPA on the results of the ongoing endometrial cancer sintilimab combination Phase II study, which may lead to NDA submission in the first half of 2024; and
- Complete enrollment of China Phase II/III study of combination with PD-1 inhibitor sintilimab in clear cell RCC (NCT05522231) around year end 2023.

Surufatinib (SULANDA® in China), an oral inhibitor of VEGFR, FGFR³⁰ and CSF-1R³¹ designed to inhibit tumor angiogenesis and promote immune response against tumor cells via tumor associated macrophage regulation

- Reported data from the Phase Ib/II China toripalimab combination study at the 2023 AACR and ASCO annual meetings (NCT04169672).

Sovleplenib (HMPL-523), an investigative and highly selective oral inhibitor of Syk³², an important component of the Fc receptor and B-cell receptor signaling pathway

- Completed enrollment of a Phase II Proof-of-Concept study in warm AIHA³³ in China (NCT05535933).

Potential upcoming clinical milestones for sovleplenib:

- Report top-line results from ESLIM-01 China Phase III in primary ITP³⁴ (NCT03951623) in 2023;
- Decide whether to proceed into Phase I in ITP in US depending on the outcome of China Phase III; and
- Decide whether to proceed into Phase III in warm AIHA in China or continue dose escalation, depending on the outcome of an upcoming analysis of a Phase II Proof-of-Concept study in warm AIHA.

Amdizalisib (HMPL-689), an investigative and highly selective oral inhibitor of PI3K δ ³⁵ designed to address the gastrointestinal and hepatotoxicity associated with currently approved and clinical-stage PI3K δ inhibitors

- Completed recruitment of patients for China registration Phase II study for the treatment of follicular lymphoma (with Breakthrough Therapy Designation) in February 2023 (NCT04849351); and
- Initiated combination trial with tazemetostat in China in February 2023 (NCT05713110).

Potential upcoming clinical and regulatory milestones for amdizalisib:

- Report top-line results from the China registration Phase II study for the treatment of follicular lymphoma in late 2023.

Tazemetostat (TAZVERIK® in Macau and the Hainan Pilot Zone), a first-in-class, oral inhibitor of EZH2 licensed from Ipsen³⁶ subsidiary Epizyme³⁷ in China

- Approved and launched in the Macau Special Administrative Region in March 2023.

Potential upcoming clinical and regulatory milestones for tazemetostat:

- Complete recruitment of a China bridging study in follicular lymphoma for conditional registration based on U.S. approvals in H2 2023 (NCT05467943).

HMPL-453, a novel, highly selective and potent inhibitor targeting FGFR 1, 2 and 3

- Reported human data for the first time at the 2023 ASCO annual meeting; and
- After consultation with NMPA, initiated the registration phase of the ongoing Phase II trial for IHCC patients with FGFR 2 fusion (NCT04353375).

Earlier stage investigational drug candidates

In addition to the seven drug candidates being developed in over 15 registration studies above, HUTCHMED is developing six further oncology candidates in early-stage clinical trials. These are **HMPL-306**, a highly selective oral inhibitor of IDH1/2³⁸ designed to address resistance to currently marketed IDH inhibitors; **HMPL-760**, a highly selective, third-generation oral inhibitor of BTK³⁹ with improved potency versus first generation BTK inhibitors against both wild type & C481S mutant enzymes; **HMPL-295**, a highly selective oral inhibitor of ERK⁴⁰ in the MAPK pathway⁴¹ with the potential to address intrinsic or acquired resistance from upstream mechanisms such as RAS-RAF-MEK; **HMPL-653**, an oral, highly selective, and potent CSF-1R inhibitor designed to target CSF-1R driven tumors as a monotherapy or in combinations; **HMPL-A83**, a differentiated, red blood cell sparing anti-CD47 antibody; and **HMPL-415**, a novel SHP2 allosteric inhibitor that entered clinical trials in July 2023.

Subject to data and consultation with the CDE⁴², several of these earlier stage drug candidates have potential to move into registration trials in the next 12 months.

IV. COLLABORATION UPDATES

Closed Exclusive Worldwide License to Takeda for Fruquintinib Outside China

- Takeda is responsible for development, manufacturing and commercialization in all indications and territories outside of mainland China, Hong Kong and Macau; and
- HUTCHMED is eligible to receive up to \$1.13 billion, including the \$400 million upfront received in April 2023, and up to \$730 million in additional potential payments relating to regulatory, development and commercial sales milestones, as well as royalties on net sales.

Further clinical progress by Inmagene with two candidates discovered by HUTCHMED

- Inmagene initiating a global, Phase II trial in adults with moderate-to-severe atopic dermatitis with IMG-007, an anti-OX40 antibody. It was safe and well-tolerated in the completed Phase I study with no reports of pyrexia or chills, which are common adverse events of rocatinlimab, another anti-OX40 treatment.
- Inmagene completed a Phase I study with IMG-004, a reversible, non-covalent, highly selective oral BTK inhibitor designed to target immunological diseases. IMG-004 was safe and well-tolerated in this single-ascending-dose study, with a long half-life and sustained pharmacodynamic effects that are well above others in its class.

V. OTHER VENTURES

Other Ventures include our profitable prescription drug marketing and distribution platforms

- Other Ventures consolidated revenues increased by 57% (67% at CER) to \$173.7 million (H1-22: \$110.9m);
- SHPL⁴³ non-consolidated joint venture revenues increased by 11% (19% at CER) to \$235.3 million (H1-22: \$212.4m);
- Consolidated net income attributable to HUTCHMED from our Other Ventures increased by 5% (12% at CER) to \$37.2 million (H1-22: \$35.4m), which was primarily due to the net income contributed from SHPL of \$35.1 million (H1-22: \$33.6m); and
- We are exploring opportunities to monetize the underlying value of our SHPL joint venture including various divestment and equity capital market alternatives.

VI. IMPACT OF COVID-19

While restrictive measures related to COVID-19 were gradually lifted in China starting from December 2022, COVID-19 had some impact on our research, clinical studies and our commercial activities in the first months of 2023. Measures were put in place to reduce the impact and, in the second quarter of 2023, these activities normalized.

VII. SUSTAINABILITY

At HUTCHMED, we are committed to a progressive journey as we continue to grow. This includes embedding sustainability into all aspects of our operations and creating long-term value for our stakeholders, including our staff, our communities and our shareholders. In April 2023, we published our [2022 Sustainability Report](#) alongside our [2022 Annual Report](#). This year we continue to make progress in line with the commitments and outcomes outlined in the report, including achieving satisfactory progress to date towards the 11 short- to long-term sustainability goals and targets and following the recommended disclosure framework of the Task Force on Climate-related Financial Disclosures (TCFD) in line with the risks assessment. In the second half of 2023, we continue enhancing our climate risks action by conducting scope 3 emissions screening, introducing a digital data collection platform, and further strengthening our sustainability-related disclosures.

FINANCIAL HIGHLIGHTS

Foreign exchange impact: The RMB depreciated against the U.S. dollar on average by approximately 7% during the six months ended June 30, 2023, which has impacted our consolidated financial results as highlighted below.

Cash, Cash Equivalents and Short-Term Investments were \$856.2 million as of June 30, 2023 compared to \$631.0 million as of December 31, 2022.

- Adjusted Group (non-GAAP⁴⁴) net cash flows excluding financing activities in the first half of 2023 were \$219.3 million (H1-22: -\$110.9m) mainly due to receipt of a \$400 million payment from Takeda; and
- Net cash generated from financing activities in the first half of 2023 totaled \$5.8 million mainly due to the proceeds of bank borrowings (H1-22: net cash used in financing activities of \$74.6m mainly due to the repayment of bank borrowings and purchases of ADSs⁴⁵ by a trustee for the settlement of equity awards).

Revenues for the six months ended June 30, 2023 were \$532.9 million compared to \$202.0 million in the six months ended June 30, 2022.

- Oncology/Immunology consolidated revenues increased 294% (301% at CER) to \$359.2 million (H1-22: \$91.1m) resulting from:
 - ELUNATE[®] revenues increased 16% (25% at CER) to \$42.0 million (H1-22: \$36.0m) due to continued market share gain, comprising of manufacturing revenues, promotion and marketing service revenues and royalties;
 - SULANDA[®] revenues increased 66% (79% at CER) to \$22.6 million (H1-22: \$13.6m) from our continuing marketing activities, increasing patient access after inclusion on the NRDL in January 2022 and long duration of treatment;
 - ORPATHYS[®] revenues increased 10% (17% at CER) to \$15.1 million (H1-22: \$13.8m) after inclusion in the NRDL effective from March 2023 and comprises of manufacturing revenues and royalties;
 - TAZVERIK[®] revenues were \$0.4 million (H1-22: \$0.1m) from further sales in the Hainan Pilot Zone;
 - Partnering revenue of \$258.7 million was the first half recognized portion of the \$400 million upfront payment from Takeda; and
 - Other R&D services income of \$20.4 million (H1-22: \$12.6m), primarily related to fees from AstraZeneca, Lilly and Takeda for the management of development and regulatory activities.
- Other Ventures consolidated revenues increased 57% (67% at CER) to \$173.7 million (H1-22: \$110.9m), mainly due to higher sales of prescription drugs. This excludes 11% (19% at CER) growth in non-consolidated revenues at SHPL of \$235.3 million (H1-22: \$212.4m).

Net Expenses for the six months ended June 30, 2023 were \$364.3 million compared to \$364.9 million for the six months ended June 30, 2022.

- Costs of Revenues** increased by 52% to \$208.3 million (H1-22: \$137.3m), of which cost of revenues from our Other Ventures increased by 63% to \$164.8 million (H1-22: \$101.0m) due to the increasing sales of third-party prescription drug products, and cost of revenues from Oncology/Immunology increased by 20% to \$43.5 million (H1-22: \$36.3m) due to the increasing sales of ELUNATE[®], SULANDA[®] and ORPATHYS[®];
- R&D Expenses** reduced 20% to \$144.6 million (H1-22: \$181.7m), mainly as a result of the strategic prioritization of our pipeline. Our international clinical and regulatory operations in the U.S. and Europe incurred expenses of \$55.6 million (H1-22: \$83.6m), while R&D expenses in China were \$89.0 million (H1-22: \$98.1m);
- SG&A Expenses** were \$68.3 million (H1-22: \$79.8m), which decreased primarily due to the restructuring of our U.S. Oncology/Immunology commercial operations at the end of 2022 while our China commercial infrastructure was able to support further revenue growth; and
- Other Items** generated net income of \$56.9 million (H1-22: \$33.9m), which increased primarily due to higher interest income earned after receiving the \$400 million Takeda upfront payment in April 2023 and foreign currency exchange gains.

Net Income attributable to HUTCHMED for the six months ended June 30, 2023 was \$168.6 million (which include \$258.7 million of the upfront payment recognized from Takeda) compared to Net Loss attributable to HUTCHMED of \$162.9 million for the six months ended June 30, 2022.

- The net income attributable to HUTCHMED for the six months ended June 30, 2023 was \$0.20 per ordinary share / \$1.00 per ADS, compared to net loss attributable to HUTCHMED of \$0.19 per ordinary share / \$0.96 per ADS for the six months ended June 30, 2022.

FINANCIAL SUMMARY

Condensed Consolidated Balance Sheets Data

(in \$'000)

	As of June 30, 2023	As of December 31, 2022
	(Unaudited)	
Assets		
Cash and cash equivalents and short-term investments	856,168	630,996
Accounts receivable	129,203	97,988
Other current assets	105,114	110,904
Property, plant and equipment	96,829	75,947
Investments in equity investees	37,740	73,777
Other non-current assets	72,443	39,833
Total assets	1,297,497	1,029,445
Liabilities and shareholders' equity		
Accounts payable	54,575	71,115
Other payables, accruals and advance receipts	227,212	264,621
Deferred revenue	149,440	13,537
Bank borrowings	40,147	18,104
Other liabilities	26,106	25,198
Total liabilities	497,480	392,575
Company's shareholders' equity	782,039	610,367
Non-controlling interests	17,978	26,503
Total liabilities and shareholders' equity	1,297,497	1,029,445

Condensed Consolidated Statements of Operations Data

(Unaudited, in \$'000, except share and per share data)

	Six Months Ended June 30	
	2023	2022
Revenues:		
Oncology/Immunology – Marketed Products	80,149	63,517
Oncology/Immunology – R&D	279,034	27,552
Oncology/Immunology consolidated revenues	359,183	91,069
Other Ventures	173,691	110,978
Total revenues	532,874	202,047
Operating expenses:		
Costs of revenues	(208,324)	(137,318)
Research and development expenses	(144,633)	(181,741)
Selling and general administrative expenses	(68,263)	(79,742)
Total operating expenses	(421,220)	(398,801)
	111,654	(196,754)
Other income/(expense), net	25,434	(3,882)
Income/(loss) before income taxes and equity in earnings of equity investees	137,088	(200,636)
Income tax (expense)/benefit	(2,730)	4,215
Equity in earnings of equity investees, net of tax	35,110	33,549
Net income/(loss)	169,468	(162,872)
Less: Net (income)/loss attributable to non-controlling interests	(917)	11
Net income/(loss) attributable to HUTCHMED	168,551	(162,861)
Earnings/(losses) per share attributable to HUTCHMED (US\$ per share)		
– basic	0.20	(0.19)
– diluted	0.19	(0.19)
Number of shares used in per share calculation		
– basic	846,928,863	849,283,553
– diluted	866,990,610	849,283,553
Earnings/(losses) per ADS attributable to HUTCHMED (US\$ per ADS)		
– basic	1.00	(0.96)
– diluted	0.97	(0.96)
Number of ADSs used in per share calculation		
– basic	169,385,773	169,856,711
– diluted	173,398,122	169,856,711

FINANCIAL GUIDANCE

Following the closing of the license with Takeda and having received from them the upfront payment of \$400 million, we currently expect to recognize approximately \$280 million in 2023.

We provide financial guidance for Oncology/Immunology consolidated revenues, reflecting expected revenue growth of our oncology products in China; R&D services income from our partners AstraZeneca, Lilly and Takeda; potential milestone payments on fruquintinib U.S. regulatory approval; and the above-mentioned recognition of the upfront payment from Takeda. We believe that we remain on track to meet the 2023 guidance provided in the announcement of our 2022 full year results on February 28, 2023.

	H1 2022 Actual	H1 2023 Actual	FY 2022 Actual	FY 2023 Guidance	Adjustments vs. Previous Guidance
Oncology/Immunology consolidated revenues	\$91.1 million	\$359.2 million	\$163.8 million	\$450 – \$550 million	Nil

Shareholders and investors should note that:

- we do not provide any guarantee that the statements contained in the financial guidance will materialize or that the financial results contained therein will be achieved or are likely to be achieved; and
- we have in the past revised our financial guidance and reference should be made to any announcements published by us regarding any updates to the financial guidance after the date of publication of this announcement.

Use of Non-GAAP Financial Measures and Reconciliation – References in this announcement to 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 and reconciliations of these financial measures to the most comparable GAAP measures, respectively.

Conference call and audio webcast presentation scheduled today at 8 p.m. HKT / 1 p.m. BST / 8 a.m. EDT. After registering, investors may access a live audio webcast of the call via HUTCHMED’s website at www.hutch-med.com/event/.

Participants who wish to join the call by telephone and ask a question must [register](#). Upon registration, each participant will be provided with dial-in numbers and a unique PIN.

HUTCHMED intends to host a Capital Markets Day in the fourth quarter of this year to further update the market on its progress following the strategy change, and to showcase the exciting pipeline of drug candidates.

About HUTCHMED

HUTCHMED (Nasdaq/AIM: HCM; HKEX: 13) is an innovative, commercial-stage, biopharmaceutical company. It is committed to the discovery, global development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. It has approximately 5,000 personnel across all its companies, at the center of which is a team of about 1,800 in oncology/immunology. Since inception, HUTCHMED has focused on bringing cancer drug candidates from in-house discovery to patients around the world, with its first three oncology medicines now approved and marketed in China. For more information, please visit: www.hutch-med.com or follow us on [LinkedIn](#).

References

Unless the context requires otherwise, references in this announcement to the “Group,” the “Company,” “HUTCHMED,” “HUTCHMED Group,” “we,” “us,” and “our,” mean HUTCHMED (China) Limited and its subsidiaries 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,” “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 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, that any approvals which are obtained will be obtained at any particular time, or that the sales of products marketed or otherwise commercialized by HUTCHMED and/or its collaboration partners (collectively, “HUTCHMED’s Products”) 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, including, among others, the risk that HUTCHMED’s ADSs could be barred from trading in the United States as a result of the Holding Foreign Companies Accountable Act and the rules promulgated thereunder; 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 the utilization, market acceptance and commercial success of HUTCHMED’s Products after obtaining regulatory approval; competing products and drug candidates that may be superior to, or more cost effective than, HUTCHMED’s Products and drug candidates; the impact of studies (whether conducted by HUTCHMED or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of HUTCHMED’s Products and drug candidates in development; the ability of HUTCHMED to manufacture and manage supply chains for multiple products and drug candidates; the availability and extent of reimbursement of HUTCHMED’s Products from third-party payers, including private payer healthcare and insurance programs and government insurance programs; the costs of developing, producing and selling HUTCHMED’s Products; the ability of HUTCHMED to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; 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, uncertainties regarding future global exchange rates and uncertainties regarding the impact of COVID-19. For further discussion of these and other risks, see HUTCHMED’s filings with the U.S. Securities and Exchange Commission, on AIM and on HKEX⁴⁶. HUTCHMED 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 HUTCHMED obtained from industry publications and reports generated by third-party market research firms. Although HUTCHMED believes that the publications, reports and surveys are reliable, HUTCHMED 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 (as it forms part of retained E.U. law as defined in the European Union (Withdrawal) Act 2018).

Ends

OPERATIONS REVIEW

ONCOLOGY/IMMUNOLOGY

We discover, develop, manufacture and market targeted therapies and immunotherapies for the treatment of cancer and immunological diseases through a fully integrated team of approximately 900 scientists and staff (December 31, 2022: ~960), and an in-house oncology commercial organization of over 900 staff (December 31, 2022: ~870).

We have 13 oncology drug candidates in clinical trials in China, with four also in active clinical development in the U.S. and Europe. Our three medicines, fruquintinib, surufatinib and savolitinib, have all been approved and launched in China and the fourth, tazemetostat, has been approved and launched in Hainan Pilot Zone and Macau, and submitted for registration in Hong Kong.

MARKETED PRODUCT SALES

Despite some initial challenges in the first quarter of the year due to the impact of COVID-19 in China, in-market sales of HUTCHMED's novel oncology products continued to grow at 16% (25% at CER) to \$101.3 million (H1-22: \$87.4m) in the first half of 2023.

Fruquintinib (ELUNATE® in China)

ELUNATE® is approved for the treatment of third-line metastatic CRC for which there is an approximate incidence of 105,000 new patients per year in China. We estimate that in the first half of 2023, approximately 17,000 (H1 2022: approximately 14,000) new patients were treated with ELUNATE® in China, despite some challenges in the first quarter of the year due to the impact of COVID-19. ELUNATE® surpassed regorafenib in prescription numbers for late-stage CRC at the end of 2021, and that lead grew to an approximately 47% market share at the end of June 2023. This resulted in in-market sales of \$56.3 million, up 12% (20% at CER) versus the first half of 2022 (\$50.4 million).

Under the terms of our agreement with Lilly, HUTCHMED manages all on-the-ground medical detailing, promotion and local and regional marketing activities for ELUNATE® in China. We consolidate as revenues approximately 70-80% of ELUNATE® in-market sales from manufacturing fees, service fees and royalties paid to us by Lilly. In the first half of 2023, we consolidated \$42.0 million in revenue for ELUNATE®, equal to 75% of in-market sales. Our commercial team continues to be highly active, celebrating ELUNATE®'s fifth year since it was approved and adding a further 112 (+17%) new hospital pharmacy listings in the first half of 2023.

ELUNATE® continues to be included in the NRDL in 2023. Negotiations with the China NHSA⁴⁷ to renew its inclusion beyond 2023 are expected to take place in the second half of this year. The new NHSA NRDL price determination scheme was published in July 2023, indicating medicines that already have reimbursement coverage will go through a simplified renewal/renegotiation process with limited further price discount, particularly for products that have been reimbursed for at least four years, such as ELUNATE®.

Outside of China, fruquintinib will be marketed by our partner Takeda. In the U.S., commercial preparations are ongoing by Takeda to be ready for launch once U.S. approval is granted.

Surufatinib (SULANDA® in China)

SULANDA® was launched in China in 2021 for the treatment of all advanced NETs⁴⁸ for which there is an approximate incidence of 34,000 new patients per year in China. In the first half of 2023, approximately 12,000 new patients were treated with SULANDA®, compared to the approximately 12,000 new patients in 2022. The two older therapies for advanced NETs approved and NRDL reimbursed in China, SUTENT® and AFINITOR®, were approved in 2012 and 2014, respectively. In the first quarter of 2023, SULANDA® had the leading share of the market at approximately 17%, compared to SUTENT and AFINITOR at 13% and 11%, respectively.

Sales growth in 2022 was strong, being the first year in which SULANDA® had been listed on the NRDL. As a result of our continued marketing activities, increasing patient access to SULANDA® and its long duration of treatment, total sales in the first half of 2023 accelerated, growing by 66% (79% at CER) to \$22.6 million (H1-22: \$13.6 million). Our commercial team added a further 103 (+19%) new hospital pharmacy listings in the first half of 2023.

Savolitinib (ORPATHYS® in China)

ORPATHYS® is the first-in-class selective MET inhibitor to be approved in China, launched and marketed by our partner, AstraZeneca for patients with MET exon 14 skipping alteration NSCLC. More than a third of the world's lung cancer patients are in China. Among those with NSCLC globally, approximately 2-3% have tumors with MET exon 14 skipping alterations.

In 2021, 2022 and the first two months of 2023, ORPATHYS® was sold as a self-pay drug. Following negotiations with the China NHA in January 2023, ORPATHYS® has been included in the updated NRDL since March 1, 2023 at a 38% discount relative to the self-pay price, broadening patient access to this medicine. Sales during the first half of 2023 were impacted by customary channel fluctuations following the announcement (in January 2023) and implementation of the NRDL listing (in March 2023), with increased volume in the latter part of the first half of 2023. In-market sales for ORPATHYS® fell 5% (increased 2% at CER) in the first half of 2023 to \$22.0 million (H1-22: \$23.3m) resulting in our consolidation of \$15.1 million (H1-22: \$13.8m) in revenues from manufacturing fees and royalties. Sales in the second quarter of 2023 were substantially higher than in the second quarter of 2022 before NRDL listing, increasing 84% by volume.

Market understanding of the need for MET testing has improved significantly, with approximately half of new advanced/relapsed NSCLC patients in China being tested. In the National Health Commission's *Treatment Guidelines for Primary Lung Cancer 2022* and the China Medical Association Oncology Committee Lung Cancer Group's *China Medical Association Guideline for Clinical Diagnosis and Treatment of Lung Cancer*, ORPATHYS® was identified as the only targeted therapy recommended for MET exon 14 patients, while a similar guideline from CSCO⁴⁹ also recommended ORPATHYS® as the standard of care for such patients. As MET testing awareness and access increases, more patients are expected to be prescribed a selective MET inhibitor.

ORPATHYS® is the first selective MET inhibitor on the market in China, representing the majority MET TKI⁵⁰ sales. Several selective MET inhibitors are in development in China, but only one is currently expected to be eligible to enter NRDL negotiations in late 2023.

In March 2023, ORPATHYS® was approved in the Macau Special Administrative Region.

Tazemetostat (TAZVERIK® in Hainan and Macau, China; the U.S. and Japan)

In May 2022, tazemetostat was approved by the Health Commission and Medical Products Administration of Hainan Province to be used in the Hainan Boao Lecheng International Medical Tourism Pilot Zone (Hainan Pilot Zone), under the *Clinically Urgently Needed Imported Drugs* scheme, for the treatment of certain patients with epithelioid sarcoma and follicular lymphoma consistent with the label as approved by the FDA. Launched in 2013 and located in China, the Hainan Pilot Zone is a destination for international medical tourism and global hub for scientific innovation, welcoming 83,900 medical tourists in 2020, according to official data. Tazemetostat was included in the 2022 CSCO guidelines for epithelioid sarcoma. 10 epithelioid sarcoma patients began treatment in the first half of 2023 (H1-22: none). Tazemetostat is included in 2023 CSCO guideline for follicular lymphoma.

In March 2023, tazemetostat was approved in the Macau Special Administrative Region. A market authorization application has been under review in Hong Kong since December 2022.

RESEARCH & DEVELOPMENT

Our strategy is aimed at accelerating our path to profitability and establishing a long-term sustainable business, by prioritizing late-stage and registrational studies in China and partnering outside of China. Selected out-licensing opportunity candidates, particularly outside of China, include soveplenib, surufatinib and HMPL-306. HUTCHMED intends to continue to run early phase development programs for selected drug candidates in U.S., E.U. and Japan where we believe we can differentiate from a global perspective.

Below is a summary update of the clinical trial progress of our investigational drug candidates. For more details about each trial, please refer to our 2022 Annual Report published in April 2023 and recent scientific publications.

Savolitinib (ORPATHYS® in China)

Savolitinib is an oral, potent, and highly selective oral inhibitor of MET. In global partnership with AstraZeneca, savolitinib is being studied in NSCLC, PRCC and gastric cancer clinical trials with about 2,000 patients to date, both as a monotherapy and in combinations. AstraZeneca has paid HUTCHMED \$85 million of the total \$140 million in upfront payments, development and approvals milestones that are potentially payable under the relevant license and collaboration agreement.

Savolitinib – Lung cancer:

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 + TAGRISSO®	SAVANNAH : 2L/3L EGFRm+ ⁵¹ ; TAGRISSO® refractory; MET+	Global	II Registration-intent	Ongoing; Data that supported Phase IIIs at WCLC 2022	NCT03778229
Savolitinib + TAGRISSO®	SAFFRON : 2L/3L EGFRm+; TAGRISSO® refractory; MET+	Global	III	Ongoing since 2022	NCT05261399
Savolitinib + TAGRISSO®	SACHI : 2L EGFR TKI refractory NSCLC; MET+	China	III	Ongoing since 2021	NCT05015608
Savolitinib + TAGRISSO®	SANOVO : Naive patients with EGFRm & MET+	China	III	Ongoing since 2021	NCT05009836
Savolitinib monotherapy	MET exon 14 skipping alterations	China	II Registration	Approved & launched in 2021; Final OS ⁵² analysis at ELCC 2022	NCT02897479
Savolitinib monotherapy	MET exon 14 skipping alterations	China	III Confirmatory	Fully enrolled in H1 2023	NCT04923945
Savolitinib + IMFINZI™	SOUND : MET-driven, EGFR wild type	China	II	Ongoing since 2022	NCT05374603

Update on combination therapies in EGFR TKI-resistant NSCLC – MET-aberration is a major mechanism for acquired resistance to both first/second-generation EGFR TKIs as well as third-generation EGFR TKIs like TAGRISSO®. Among patients who experience disease progression post-TAGRISSO® treatment, approximately 15-50% present with MET aberration. The prevalence of MET amplification and overexpression may differ depending on the sample type, detection method and assay cut-off used. Savolitinib has been studied extensively in these patients in the TATTON (NCT02143466) and **SAVANNAH** (NCT03778229) studies. The encouraging results led to the initiation and planning of three Phase III studies: **SACHI** and **SANOVO** were initiated in China in 2021, and the global, pivotal Phase III **SAFFRON** study is currently open for enrollment.

The **SAVANNAH global Phase II** study, in patients who have progressed following TAGRISSO® due to MET amplification or overexpression, is expected to complete recruitment in the second half of 2023. In January 2023, the **U.S. FDA designated as a Fast Track** development program the investigation of savolitinib for use in combination with TAGRISSO® for the treatment of patients with locally advanced or metastatic NSCLC whose tumors have MET overexpression and/or amplification, as detected by an FDA-approved test, and who have had disease progression during or following prior TAGRISSO®. We continue to evaluate the possibility of using the **SAVANNAH** study as the basis for U.S. accelerated approval.

The **SAFFRON** study, which will evaluate the efficacy and safety of savolitinib in combination with TAGRISSO® compared to pemetrexed plus platinum doublet-chemotherapy, has now activated a majority of the approximately 250 sites in over 20 countries planned for the study, although enrollment of **SAVANNAH** is being prioritized until it is fully enrolled.

Two registrational studies are ongoing in China in EGFR mutated NSCLC with MET aberrations: the **SANOVO** study in treatment naïve patients, and **SACHI** study in patients whose disease progressed following treatment with any first-line EGFR TKI. Both trials are expected to complete enrollment in 2024.

Update on MET altered, EGFR wild type NSCLC in China – The June 2021 monotherapy approval by the NMPA was based on positive results from a Phase II trial conducted in China in patients with NSCLC with MET exon 14 skipping alterations (NCT02897479). A confirmatory study in this patient population fully enrolled in H1 2023 (NCT04923945). Results from the first-line cohort of this study are accepted for disclosure by WCLC.

Savolitinib – Kidney cancer:

MET is a key genetic driver in papillary RCC, and emerging evidence suggests that combining immunotherapies with a MET inhibitor could enhance anti-tumor activity. PRCC is a subtype of kidney cancer, representing about 15% of patients, with no treatments approved for patients with tumors that harbor MET-driven alterations. Savolitinib has been studied in multiple global studies in PRCC patients, including the SAVOIR monotherapy and CALYPSO combination therapy global Phase II trials, that both demonstrated highly encouraging results. These results led to the initiation of a global Phase III, the SAMETA study, in 2021. Over 140 sites in over 20 countries are enrolling patients.

The table below shows a summary of the clinical study for savolitinib in kidney cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib + IMFINZI®	SAMETA: MET-driven, unresectable and locally advanced or metastatic PRCC	Global	III	Ongoing since 2021	NCT05043090

Savolitinib – Gastric cancer:

MET-driven gastric cancer has a very poor prognosis. Multiple Phase II studies have been conducted in Asia to study savolitinib in MET-driven gastric cancer, of which approximately 5% of all gastric cancer patients, demonstrated promising efficacy, including VIKTORY. The VIKTORY study reported a 50% ORR⁵³ with savolitinib monotherapy in gastric cancer patients whose tumors harbor MET amplification.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib	2L+ gastric cancer with MET amplification. Two-stage, single-arm study	China	II registration-intent	~65 patient registration cohort enrolling since March 2023	NCT04923932

Preliminary efficacy and safety data from an interim analysis of 20 patients in a Phase II trial of savolitinib monotherapy in patients with MET-amplified advanced or metastatic gastroesophageal junction adenocarcinomas or gastric cancer was reported at AACR 2023, showing promising efficacy in patients with MET-amplified diseases, particularly in patients with high MET gene copy number. Confirmed ORR by independent review was 45%, or 50% in the 16 patients with high MET gene copy number. Duration of response rate at 4-months was 85.7%. The most common grade 3 or above TRAEs (more than 5%) were decreased platelet count, hypersensitivity, anemia, neutropenia and abnormal hepatic function. The BID regimen is being investigated to further evaluate the efficacy and safety of savolitinib in MET high patients. Following consultation with the NMPA with this data, a patient registration cohort began enrolling in March 2023.

Fruquintinib (ELUNATE® in China)

Fruquintinib is a novel, selective, oral inhibitor of VEGFR 1/2/3 kinases that was designed to improve kinase selectivity to minimize off-target toxicity and thereby improve efficacy and tolerability. Fruquintinib has been studied in clinical trials with about 5,500 patients to date, both as a monotherapy and in combination with other agents.

Aside from its first approved indication of third-line CRC (in China), studies of fruquintinib combined with various checkpoint inhibitors (including TYVYT® and tislelizumab) are underway. Registration-intent studies combined with chemotherapy (FRUTIGA study in gastric cancer) or checkpoint inhibitors (TYVYT® combo, in endometrial cancer and RCC) are ongoing in China.

We are partnered with Lilly in China and with Takeda outside of 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-2: metastatic CRC	U.S. / Europe / Japan / Aus.	III	U.S. PDUFA date Nov 30, 2023, EMA MAA validated in Jun 2023; Japan filing in 2023; Results published in <i>The Lancet</i> ; further data presented at ASCO GI, JSMO ⁵⁴ & ASCO 2023	NCT04322539
Fruquintinib monotherapy	CRC; TN ⁵⁵ & HR+ ⁵⁶ /Her2- ⁵⁷ breast cancer	U.S.	I/Ib	CRC data at ASCO GI 2022; results supported the initiation of the FRESCO-2	NCT03251378

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Fruquintinib + tislelizumab (PD-1)	MSS ⁵⁸ -CRC	U.S.	Ib/II	Ongoing since 2021; Fully enrolled; Follow-up ongoing; Conference submission pending completion of follow-up	NCT04577963
Fruquintinib monotherapy	FRESCO : ≥ 3L CRC; chemotherapy refractory	China	III	Approved & launched in 2018	NCT02314819
Fruquintinib + paclitaxel	FRUTIGA : 2L gastric cancer	China	III	Supplemental NDA accepted by NMPA in Apr 2023	NCT03223376
Fruquintinib + TWYT [®] (PD-1)	CRC	China	II	Data published in <i>European Journal of Cancer</i>	NCT04179084
Fruquintinib + TWYT [®] (PD-1)	Endometrial cancer	China	II registration-intent	Fully enrolled; if positive, NDA filing H1 2024; Ib data at CSCO 2021	NCT03903705
Fruquintinib + TWYT [®] (PD-1)	RCC	China	Ib/II	Fully enrolled; Updated data at ASCO 2023	NCT03903705
Fruquintinib + TWYT [®] (PD-1)	RCC	China	II/III	Ongoing since 2022	NCT05522231
Fruquintinib + TWYT [®] (PD-1)	Gastrointestinal tumors, NSCLC, cervical cancer	China	Ib/II	Fully enrolled	NCT03903705
Fruquintinib + tislelizumab (PD-1)	CRC	Korea / China	Ib/II	Fully enrolled	NCT04716634

Fruquintinib – CRC updates:

[FRESCO-2 \(NCT04322539\)](#) – Positive results from this double-blind, placebo-controlled, global Phase III study in 691 patients with refractory metastatic CRC were presented at ESMO 2022 and subsequently published in *The Lancet*. The study demonstrated that treatment with fruquintinib resulted in a statistically significant and clinically meaningful increase in OS and the key secondary endpoint of PFS⁵⁹ compared to treatment with placebo. The safety profile of fruquintinib in FRESCO-2 was consistent with previously reported fruquintinib studies.

Further analyses presented at ASCO GI and ASCO 2023 added to the understanding of fruquintinib efficacy and safety. At ASCO GI, results showed that health-related quality of life was not negatively impacted by treatment with fruquintinib.

ASCO presentations showed that in subgroup analyses by prior lines of therapies up to six or more and by prior treatment with approved agents, fruquintinib improved OS and PFS for all subgroups and prior therapies, consistent with those of the overall study population. A separate study showed that during the study adverse events of special interest led to low rates of dose reduction (13.6% for patients who received fruquintinib vs 0.9% for patients who received placebo) and dose discontinuation (8.3% for patients who received fruquintinib vs 6.1% for patients who received placebo).

Outcomes from the Japanese cohort was presented at JSMO 2023. Fruquintinib treatment led to results for Japanese patients in the study consistent with the overall study population.

Filing of a rolling submission of an NDA was accepted by the FDA in May 2023 for priority review, with PDUFA date of November 30, 2023. MAA filing to the EMA was validated in June 2023. NDA filing to the PMDA is expected to follow in 2023.

[China Phase IV \(NCT04005066\)](#) – Results presented at ASCO 2023 from a prospective, 3,005-patient study to evaluate the safety of fruquintinib in real-world clinical practice in China are consistent with the fruquintinib safety profile observed in existing clinical studies, with no new or significant safety signals identified.

Fruquintinib – Gastric cancer updates:

[FRUTIGA \(NCT03223376\)](#) – This randomized, double-blind, Phase III study in China to evaluate fruquintinib combined with paclitaxel compared with paclitaxel monotherapy, for second-line treatment of advanced gastric cancer, enrolled approximately 700 patients in July 2022. Its co-primary endpoints are PFS and OS. The trial met the PFS endpoint at a statistically and clinically meaningful level. The OS endpoint was not statistically significant per the pre-specified statistical plan, although there was an improvement in median OS. Fruquintinib also demonstrated a statistically significant improvement in secondary endpoints including ORR, DCR⁶⁰ and DoR⁶¹. The safety profile of fruquintinib in FRUTIGA was consistent with previously reported studies. In April 2023, the NDA in China was accepted for review by the NMPA. Full detailed results are subject to ongoing analysis and are expected to be disclosed at an upcoming scientific meeting.

Fruquintinib – Combinations with checkpoint inhibitors updates:

Advanced endometrial cancer registration-intent cohort of TYWT® combination (NCT03903705) – Platinum-based systemic chemotherapy is the standard first-line treatment for advanced endometrial cancer in China. However, patients who progress following first-line therapy have limited treatment options, and the prognosis remains poor. Initially presented at CSCO 2021, data in this endometrial cancer cohort is encouraging.

We agreed with the NMPA to expand this cohort into a single-arm registrational Phase II study. In July 2023, the cohort fully enrolled and was granted Breakthrough Therapy Designation. Favorable results from this trial could lead to a regulatory approval application to the NMPA in this treatment setting in 2024.

Advanced metastatic clear-cell renal cell carcinoma (NCT05522231) – In first-line clear-cell RCC, clinical benefits have been demonstrated for the combination of antiangiogenic therapy and immunotherapy. However, there is limited evidence on the benefits of this combination in the second-line setting. Phase II (NCT03903705) data disclosed at ASCO 2023 showed encouraging anti-tumor efficacy and durability in these patients. PFS results from this exploratory study of the fruquintinib and sintilimab combination in metastatic clear-cell RCC were reported. At data cut-off on November 30, 2022, median PFS was 15.9 months in 20 previously treated patients. No new safety signals were observed.

A Phase II/III trial of fruquintinib in combination with TYWT® as second-line treatment for locally advanced or metastatic RCC was initiated in October 2022. The study is a randomized, open-label, active-controlled study to evaluate the efficacy and safety of fruquintinib in combination with TYWT® versus axitinib or everolimus monotherapy for the second-line treatment of advanced RCC. The primary endpoint is PFS. Approximately 260 patients will be enrolled in the study.

Fruquintinib – Exploratory development:

In China, we support an investigator initiated trial program for fruquintinib, and there are over 50 of such trials ongoing in various solid tumor settings. A number of investigator-initiated trials were presented at ASCO 2023, including initial results of a Phase II study of fruquintinib in combination with investigator’s choice of chemotherapy in second-line metastatic CRC with microsatellite stable (MSS) phenotype, as well as fruquintinib monotherapy for the treatment of biliary tract cancer and soft tissue sarcoma.

Fruquintinib – Partnership with Takeda:

In January 2023, HUTCHMED entered into an exclusive worldwide license to develop and commercialize fruquintinib in all indications and territories outside of mainland China, Hong Kong and Macau, where it is marketed and will continue to be marketed by HUTCHMED in partnership with Lilly. Subject to the terms of the agreement, HUTCHMED will be eligible to receive up to \$1.13 billion, including \$400 million which was received in April 2023 on closing of the agreement, and up to \$730 million in additional potential payments relating to regulatory, development and commercial sales milestones, as well as royalties on net sales.

Surufatinib (SULANDA® in China)

Surufatinib is a novel, oral angio-immuno kinase inhibitor that selectively inhibits the tyrosine kinase activity associated with VEGFR and FGFR, both shown to be involved in tumor angiogenesis, and CSF-1R, which plays a key role in regulating tumor-associated macrophages, promoting the body’s immune response against tumor cells. Surufatinib has been studied in clinical trials with around 1,800 patients to date, both as a monotherapy and in combinations, and is approved in China. HUTCHMED currently retains all rights to surufatinib worldwide.

Surufatinib’s ability to inhibit angiogenesis, block the accumulation of tumor associated macrophages and promote infiltration of effector T cells into tumors could help improve the anti-tumor activity of PD-1 antibodies. Several combination studies with PD-1 antibodies have shown promising data. A summary of the clinical studies of surufatinib is shown in the table below.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Surufatinib monotherapy	NETs	Japan	Bridging	Ongoing since 2021	NCT05077384
Surufatinib monotherapy	SANET-ep: epNET ⁶²	China	III	Approved; Launched in 2021	NCT02588170
Surufatinib monotherapy	SANET-p: pNET ⁶³	China	III	Approved; Launched in 2021	NCT02589821
Surufatinib + TUOYI* (PD-1)	SURTORI-01: 2L NEC ⁶⁴	China	III	Ongoing since 2021	NCT05015621
Surufatinib + TUOYI* (PD-1)	NENs ⁶⁵ , GC, ESCC, SCLC ⁶⁶ , NSCLC, EMC, TC, STS, BTC	China	II	Fully enrolled; Data at AACR 2023 & ASCO 2023	NCT04169672
Surufatinib + TUOYI* (PD-1)	SCLC	China	II	Ongoing since 2022	NCT05509699

Surufatinib – Monotherapy in NET updates:

Ex-China regulatory discussions – Surufatinib received FDA Fast Track Designations in April 2020 for the treatment of pNETs and epNETs. Orphan Drug Designation for pNETs was granted in November 2019. While discussions in 2020 suggested that two positive Phase III studies of surufatinib in patients with pNETs and epNETs in China, could form the basis to support a U.S. NDA submission, this was ultimately not accepted. A new multi-regional clinical trial (MRCT) would be required to move forward with this program in the U.S., Europe and Japan. Following dialogue with the Japanese PMDA, we have decided not to file a Japanese NDA on the basis of the clinical trial data available at this time.

Surufatinib – Combination therapy with checkpoint inhibitors:

A Phase II China study (NCT04169672) combining surufatinib with TUOYI* enrolled patients in nine solid tumor types, including NENs, biliary tract cancer, gastric cancer, thyroid cancer, SCLC, soft tissue sarcoma, endometrial cancer, esophageal cancer and NSCLC. These have led to the initiation in September 2021 of the first Phase III trial combining surufatinib with a PD-1 antibody, the SURTORI-01 study in NEC and a Phase II study in SCLC in 2022.

We reported the results from the advanced thyroid cancer and endometrial cancer cohorts at ASCO 2023. Amongst efficacy evaluable radioactive iodine-refractory differentiated thyroid cancer patients, median PFS was 10.9 months and median OS was not reached (median follow-up duration was 22.1 months). Amongst efficacy evaluable endometrial cancer patients, median PFS was 5.4 months and 12-month OS rate was 71.0% (median follow-up duration was 16.8 months). In both cohorts, the combination showed a tolerable safety profile. Additionally, results from the NSCLC cohort were presented at AACR 2023 demonstrating promising anti-tumor activity in first-line setting for advanced PD-L1 positive NSCLC patients with manageable toxicity.

Surufatinib – Exploratory development:

In China, we support an investigator-initiated trial program for surufatinib, with over 80 of such trials in various solid tumor settings being conducted for both combination and single agent regimens. These trials explore and answer important medical questions in addition to our own company-sponsored clinical trials. A number of investigator initiated trials were presented at ASCO 2023 for surufatinib in combination with other agents, including with chemotherapy as well as with camrelizumab (an anti-PD-1 antibody) plus different chemotherapy regimens in various solid types including pancreatic adenocarcinoma and NSCLC.

Hematological Malignancies Candidates

HUTCHMED currently has six investigational drug candidates targeting hematological malignancies in clinical development. **Sovleplenib** (HMPL-523, targeting Syk), **amdizalisib** (HMPL-689, targeting PI3K δ), and **HMPL-760** (targeting BTK) are being studied in several trials against B-cell dominant malignancies. In addition to the three B-cell receptor pathway inhibitors, HUTCHMED is also developing **HMPL-306** (targeting IDH1 and IDH2), **tazemetostat** (a methyltransferase inhibitor of EZH2) and **HMPL-A83** (an anti-CD47 monoclonal antibody).

Sovleplenib (HMPL-523)

Sovleplenib is a novel, selective, oral inhibitor targeting Syk, for the treatment of hematological malignancies and immune diseases. Syk is a component in Fc receptor and B-cell receptor signaling pathway. Sovleplenib has been studied in clinical trials with around 500 patients to date.

In December 2022, we completed recruitment of a Phase III study in China for primary ITP, for which it has received Breakthrough Therapy Designation, and presented proof of concept data on both primary ITP and hematological malignancies at ASH⁶⁷ 2021. HUTCHMED currently retains all rights to soveleplenib worldwide. The table below shows a summary of the clinical studies for soveleplenib.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Sovleplenib monotherapy	ESLIM-01: ≥ 2 L ITP	China	III	Fully enrolled; Topline results expected in H2 2023; Breakthrough Therapy Designation	NCT05029635
Sovleplenib monotherapy	Indolent NHL ⁶⁸	U.S. / Europe	I/Ib	Ongoing; Prelim. Data at ASH 2021	NCT03779113
Sovleplenib monotherapy	Warm AIHA	China	II/III	Phase II fully enrolled; Phase III decision in 2023 pending Phase II results	NCT05535933

ESLIM-01 (Evaluation of Sovleplenib for immunological diseases-01, NCT05029635) – In October 2021, we initiated a randomized, double-blinded, placebo-controlled Phase III trial in China of soveleplenib in 188 adult patients with primary ITP who have received at least one prior line of standard therapy. ITP is an autoimmune disorder that can lead to increased risk of bleeding. The primary endpoint of the study is the durable response rate. In January 2022, the NMPA granted Breakthrough Therapy Designation for this indication. Enrollment was completed in December 2022 and we expect to release topline results in the second half of 2023.

China Phase II/III in warm AIHA – This is a randomized, double-blind, placebo-controlled Phase II/III study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of soveleplenib in the treatment of warm AIHA. AIHA is the result of destruction of red blood cells due to the production of antibodies against red blood cells which bind to antigens on the red blood cell membrane in autoimmune disorders. If the results of the Phase II stage of the study indicate sufficiently satisfactory efficacy and safety, the Phase III stage will be initiated. The first patient was enrolled in September 2022. The enrollment of Phase II part of the study was completed in mid-2023, and the results will lead to a decision on whether to initiate Phase III.

Amdizalisib (HMPL-689)

Amdizalisib is a novel, highly selective oral inhibitor targeting the isoform PI3K δ , a key component in the B-cell receptor signaling pathway. Amdizalisib's pharmacokinetic properties have been found to be favorable with good oral absorption, moderate tissue distribution and low clearance in preclinical studies. We also expect that amdizalisib will have low risk of drug accumulation and drug-drug interactions, supporting feasibility of development in combination with other drugs. The first of such activities is in combination with tazemetostat. Amdizalisib has been studied in clinical trials with around 400 patients to date. HUTCHMED currently retains all rights to amdizalisib worldwide. The table below shows a summary of the clinical studies for amdizalisib.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Amdizalisib monotherapy	Indolent NHL, peripheral T-cell lymphomas	China	Ib	Ongoing; Updated data presented at ICML 2023	NCT03128164
Amdizalisib monotherapy	3L Relapsed/refractory follicular lymphoma	China	II registration-intent	Fully enrolled; Breakthrough Therapy Designation	NCT04849351
Amdizalisib monotherapy	2L Relapsed/refractory marginal zone lymphoma	China	II registration-intent	Ongoing since Apr 2021	NCT04849351

Phase II registration-intent trial (NCT04849351) – In April 2021, we commenced a registration-intent, single-arm, open-label Phase II trial in China in approximately 100 patients with relapsed/refractory follicular lymphoma and approximately 80 patients with relapsed/refractory marginal zone lymphoma, two subtypes of non-Hodgkin's lymphoma. The primary endpoint is ORR. The trial is being conducted in over 35 sites in China, has fully enrolled the follicular lymphoma cohort and the marginal zone lymphoma cohort enrollment is ongoing.

Phase Ib expansion study in relapsed/refractory lymphoma (NCT03128164) – This is an open-label study to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of amdizalisib in relapsed and/or refractory non-Hodgkin lymphoma patients. Updated safety data in all patients at recommended Phase II dose (RP2D), as well as updated efficacy data from the follicular lymphoma, marginal zone lymphoma, mantle cell lymphoma and peripheral T cell lymphoma cohorts were reported at ICML in June 2023. At median follow-up duration of 22.1 months, median DoR and PFS were not reached for the 26 efficacy evaluable patients in the follicular lymphoma cohort. PFS and DoR from the marginal zone lymphoma cohort were presented

for the first time, at median follow-up duration of 20.3 months. Median DoR was not reached and median PFS was 26.8 months for the 16 efficacy evaluable patients in this cohort. Amdizalisib showed an acceptable safety profile and promising anti-tumor activity in relapsed/refractory lymphoma.

Tazemetostat

In August 2021, we entered into a strategic collaboration with Epizyme, a subsidiary of Ipsen, to research, develop, manufacture and commercialize tazemetostat in Greater China, including the mainland, Hong Kong, Macau and Taiwan. Tazemetostat is an inhibitor of EZH2 developed by Ipsen that is approved by the U.S. FDA for the treatment of certain epithelioid sarcoma and follicular lymphoma patients. It received accelerated approval from the FDA based on ORR and DoR in January and June 2020 for epithelioid sarcoma and follicular lymphoma, respectively. Tazemetostat has been studied in clinical trials with around 1,200 patients to date.

We are developing and plan to seek approval for tazemetostat in various hematological and solid tumors in China. We are participating in Ipsen's SYMPHONY-1 (EZH-302) study, leading it in China. We are generally responsible for funding all clinical trials of tazemetostat in China, including the portion of global trials conducted there. Separately, we are conducting a China bridging study in follicular lymphoma for potential conditional registration based on its U.S. approvals. We also initiated a Phase II study in combination with our PI3K δ inhibitor amdizalisib in patients with relapsed or refractory lymphoma in February 2023. We are responsible for the research, manufacturing and commercialization of tazemetostat in China. Tazemetostat was approved in China Hainan Pilot Zone in 2022 and the Macau Special Administrative Region in 2023.

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

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Tazemetostat monotherapy	Metastatic or locally advanced epithelioid sarcoma; Relapsed/refractory 3L+ follicular lymphoma	Hainan, Macau	N/A – Hainan Pilot Zone, Macau	Approved; Launched in 2022 and 2023, respectively	N/A
Tazemetostat + lenalidomide + rituximab (R ²)	SYMPHONY-1: 2L follicular lymphoma	Global	Ib/III	Ongoing; PhIb data at ASH 2022; China portion of global Ph III started H2 2022	NCT04224493
Tazemetostat monotherapy	Relapsed/refractory 3L+ follicular lymphoma	China	II registration-intent (bridging)	Ongoing since July 2022; EZH2-wildtype cohort fully enrolled; EZH2-mutant cohort enrolling	NCT05467943
Tazemetostat + amdizalisib	Lymphoma sub-types	China	II	Ongoing since Feb 2023	NCT05713110

China Phase II combination study in relapsed/refractory follicular lymphoma (NCT05713110) – This is an open-label, Phase II study in approximately 140 patients to evaluate the safety, tolerability and preliminary anti-tumor efficacy of tazemetostat in combination with amdizalisib in patients with R/R lymphoma. The first patient was dosed in February 2023.

HMPL-453

HMPL-453 is a novel, selective, oral inhibitor targeting FGFR 1/2/3. Aberrant FGFR signaling is associated with tumor growth, promotion of angiogenesis, as well as resistance to anti-tumor therapies. Approximately 10-15% of IHCC patients have tumors harboring FGFR2 fusion. HUTCHMED currently retains 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	2L Cholangiocarcinoma (IHCC with FGFR fusion)	China	II	Ongoing since 2020; Registration cohort enrolling since March 2023	NCT04353375
HMPL-453 + chemotherapies	Multiple	China	I/II	Ongoing since 2022	NCT05173142
HMPL-453 + TUOYI [®] (PD-1)	Multiple	China	I/II	Ongoing since 2022	NCT05173142

China Phase II in IHCC (NCT04353375) – This is an open-label, single-arm Phase II study to evaluate the efficacy and safety of HMPL-453 in the treatment of patients with advanced IHCC harboring FGFR2 fusions/rearrangements after at least one line of systemic treatment failure or intolerance. Results from 25 patients treated with two different dosing regimens were presented

at the ASCO 2023 annual meeting, supporting the choice of a recommended Phase II dose. After consultation with the CDE, a monotherapy registration trial design was agreed, and the first patient was enrolled in March 2023.

HMPL-306

HMPL-306 is a novel dual-inhibitor of IDH1 and IDH2 enzymes. IDH1 and IDH2 mutations have been implicated as drivers of certain hematological malignancies, gliomas and solid tumors, particularly among acute myeloid leukemia patients. HUTCHMED currently retains all rights to HMPL-306 worldwide. The table below shows a summary of the clinical studies for HMPL-306.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-306 monotherapy	Hematological malignancies	China	I	Ongoing since 2020; RP2D determined; Dose escalation data at EHA 2023	NCT04272957
HMPL-306 monotherapy	Solid tumors including but not limited to gliomas, chondrosarcomas or cholangiocarcinomas	U.S.	I	Ongoing since 2021	NCT04762602
HMPL-306 monotherapy	Hematological malignancies	U.S.	I	Ongoing since 2021	NCT04764474

China Phase I in hematological malignancies (NCT04272957) – This is a two-phase, open-label Phase I study to evaluate the safety, pharmacokinetics, pharmacodynamics and efficacy of HMPL-306 in patients of relapsed or refractory hematological malignancies harboring IDH1 and/or IDH2 mutations. The dose escalation phase of the study is completed. The first-in-human dose-escalation phase data was presented at EHA Annual Meeting in June 2023. Based on the pharmacodynamic, pharmacokinetic and preliminary clinical findings, a recommended Phase II dose was nominated for the dose expansion phase of the study.

HMPL-760

HMPL-760 is an investigational, non-covalent, third-generation BTK inhibitor. It is a highly potent, selective, and reversible inhibitor with long target engagement against BTK, including wild-type and C481S-mutated BTK. China Phase I studies opened in early 2022 will include relapsed or refractory B-cell non-Hodgkin's lymphoma or CLL⁶⁹ patients with or without a prior regimen containing a BTK inhibitor. HUTCHMED currently retains all rights to HMPL-760 worldwide.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-760 monotherapy	CLL, SLL ⁷⁰ , other B-NHL	China	I	Ongoing since Jan 2022	NCT05190068

HMPL-295

HMPL-295 is a novel ERK inhibitor. ERK is a downstream component of the RAS-RAF-MEK-ERK signaling cascade (MAPK pathway). This is our first of multiple candidates in discovery targeting the MAPK pathway, followed by HMPL-415 targeting SHP2. A China Phase I study was initiated in July 2021 for HMPL-295. HUTCHMED currently retains all rights to HMPL-295 worldwide.

RAS-MAPK pathway is dysregulated in cancer, in which mutations or non-genetic events hyper-activate the pathway in up to 50% of cancers. RAS and RAF predict worse clinical prognosis in a wide variety of tumor types, mediate resistance to targeted therapies, and decrease the response to the approved standards of care, namely, targeted therapy and immunotherapy. ERK inhibition has the potential to overcome or avoid the intrinsic or acquired resistance from the inhibition of RAS, RAF and MEK upstream mechanisms.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-295 monotherapy	Solid tumors	China	I	Ongoing since 2021	NCT04908046

HMPL-653

HMPL-653 is a novel, highly selective, and potent CSF-1R inhibitor designed to target CSF-1R driven tumors as a monotherapy or in combination with other drugs. We initiated a China Phase I study in January 2022. HUTCHMED currently retains all rights to HMPL-653 worldwide.

CSF-1R is usually expressed on the surface of macrophages and can promote growth and differentiation of macrophages. Studies have shown that blocking the CSF-1R signaling pathway could effectively modulate the tumor microenvironment, relieve tumor immunosuppression, and synergize with other anti-cancer therapies such as immune checkpoint inhibitors to achieve tumor inhibition. It has been demonstrated in several clinical studies that CSF-1R inhibitors could treat tenosynovial giant cell tumors, and treat a variety of malignancies in combinations. Currently no CSF-1R inhibitor has been approved in China.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-653 monotherapy	Solid tumors & tenosynovial giant cell tumors	China	I	Ongoing since Jan 2022; ~110 expected to be enrolled	NCT05190068

HMPL-A83

HMPL-A83 is an investigational IgG4-type humanized anti-CD47 monoclonal antibody that exhibits high affinity for CD47. HMPL-A83 blocks CD47 binding to Signal regulatory protein (SIRP) α and disrupts the “do not eat me” signal that cancer cells use to shield themselves from the immune system. In preclinical studies, HMPL-A83 demonstrated a high affinity for CD47 antigen on tumor cells and strong phagocytosis induction of multiple tumor cells, as well as weak affinity for red blood cells and no induction of hemagglutination, implying low risk of anemia, a potential event of special interest. HMPL-A83 has also demonstrated strong anti-tumor activity in multiple animal models. HUTCHMED currently retains all rights to HMPL-A83 worldwide.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-A83 monotherapy	Advanced malignant neoplasms	China	I	Ongoing since July 2022	NCT05429008

HMPL-415

HMPL-415 is a novel SHP2 allosteric inhibitor. A China Phase I study was initiated in July 2023. HUTCHMED currently retains all rights to HMPL-415 worldwide.

SHP2 is a non-receptor protein tyrosine phosphatase ubiquitously expressed mainly in the cytoplasm of several tissues. SHP2 modulates diverse cell signaling events that control metabolism, cell growth, differentiation, cell migration, transcription and oncogenic transformation. It interacts with diverse molecules in the cell, and regulates key signaling events including RAS/ERK, PI3K/AKT, JAK/STAT and PD-1 pathways downstream of several receptor tyrosine kinases (RTKs) upon stimulation by growth factors and cytokines. This is the second of multiple candidates to have emerged from our discovery research that targets this pathway, the first being HMPL-295. Dysregulation of SHP2 expression or activity causes many developmental diseases, and hematological and solid tumors.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
HMPL-415 monotherapy	Solid tumors	China	I	Ongoing since 2023	NCT05886374

Immunology Collaboration with Inmagene

We have a strategic partnership with Inmagene, a clinical development stage company with a focus on immunological diseases, to further develop novel preclinical drug candidates we discovered for the potential treatment of multiple immunological diseases. Funded by Inmagene, we worked together to move two drug candidates towards clinical trials. Inmagene advanced the drug candidates through global clinical development.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
IMG-007 (OX40 antibody)	Adults with moderate to severe atopic dermatitis	Global	II	Open for enrollment in July 2023	Pending
IMG-007 (OX40 antibody)	Adult healthy volunteers	Australia	I	Single ascending dose completed	NCT05353972
IMG-004 (BTK inhibitor)	Adult healthy volunteers	Global	I	Single ascending dose completed	NCT05349097

IMG-007 in atopic dermatitis – This is a novel antagonistic monoclonal antibody targeting the OX40 receptor. OX40 is a costimulatory receptor member of the tumor necrosis factor receptor (TNFR) superfamily expressed predominantly on activated T cells. A global, proof-of-concept trial in adult patients with moderate-to-severe atopic dermatitis is open for enrollment. This follows a Phase I single ascending dose study in healthy volunteers that demonstrated that IMG-007, up to 600 mg, was safe and well-tolerated, with no reports of pyrexia or chills, which were common adverse events of rocatinlimab, another OX40 antibody treatment. At projected therapeutic dose levels, IMG-007 also demonstrated a mean terminal half-life of 31-37 days. The long half-life combined with a potentially improved safety profile supports IMG-007’s best-in-class potential as an OX40 targeted therapy.

IMG-004 in immunological diseases – This is a small molecule inhibitor that binds to BTK in a non-covalent, reversible manner. Designed specifically for inflammatory and autoimmune diseases that usually require long-term treatment, IMG-004 is potent, highly selective and brain permeable. A Phase I single ascending dose study in healthy volunteers in the U.S., initiated in August 2022, has recently completed. It showed that IMG-004 was safe and well-tolerated with a long half-life and sustained pharmacodynamic effects, supporting further clinical development. Results will be submitted to an upcoming medical conference.

MANUFACTURING

We continue to use contract manufacturing organizations in China to produce our clinical and commercial API⁷¹ supplies. For manufacturing drug products, we currently use a combination of contract manufacturers and our internal manufacturing facility.

We have a drug product facility in Suzhou which manufactures both clinical and commercial supplies for some of our products. We have also completed construction of a new drug product facility in Pudong, Shanghai, which will increase our novel drug product manufacturing capacity by over five times. The qualification of the Shanghai facility and its equipment is underway and is expected to be completed in the second half of 2023. The clinical manufacturing and technology transfer for some of our commercial products is expected to start in the next few months. This is in line with our previously outlined expectations of manufacturing clinical supplies from the new facility starting in 2023 and commercial supplies around 2025, after the necessary regulatory filings and approvals.

We completed technology transfer for the API and drug product of amdizalisib and soveplenib into the selected commercial manufacturing facilities in preparation for potential NDA filings. Process validation for these products (both API and drug product) are now complete.

We completed the NDA enabling work related to manufacturing for the global launch of fruquintinib at the commercial manufacturing sites. Process validation for API of this product was completed last year, and process validation for drug product at our Suzhou facility was completed earlier this year. A second drug product facility in Switzerland is also planned to be qualified in the second half of 2023, in anticipation for a potential European approval.

OTHER VENTURES

Our Other Ventures include drug marketing and distribution platforms covering about 290 cities and towns in China with over 3,000 mainly manufacturing and commercial personnel. Built over the past 20 years, it primarily focuses on prescription drugs and science-based nutrition products through several joint ventures and subsidiary companies.

In the first six months of 2023, our Other Ventures delivered encouraging growth with consolidated revenues up 57% (67% at CER) to \$173.7 million (H1-22: \$110.9m). Consolidated net income attributable to HUTCHMED from our Other Ventures increased by 5% (12% at CER) to \$37.2 million (H1-22: \$35.4m).

Hutchison Sinopharm⁷²: Our prescription drugs commercial services business, which in addition to providing certain commercial services for our own products, provides services to third-party pharmaceutical companies in China, grew sales by 68% (79% at CER) to \$166.7 million in the first half of 2023 (H1-22: \$99.3m).

In 2021, the Hong Kong International Arbitration Centre made a final award in favor of Hutchison Sinopharm against Luye⁷³ in the amount of RMB253.2 million (\$35.4 million), plus costs and interest (the “Award”), in connection with the termination of Hutchison Sinopharm’s right to distribute SEROQUEL® in China. In June 2022, Luye provided a bank guarantee of up to RMB286.0 million to cover the Award, pending the outcome of an application by Luye to the High Court of Hong Kong to set aside the Award. On July 26, 2022, Luye’s application to set aside the Award was dismissed by the High Court with costs awarded in favor of Hutchison Sinopharm. On June 6, 2023, an appeal hearing filed by Luye was heard by the Court of Appeal in Hong Kong and judgement is awaited.

SHPL: Our own-brand prescription drugs business, operated through our non-consolidated joint venture SHPL, grew sales by 11% (19% at CER) to \$235.3 million (H1-22: \$212.4m). This sales growth and favorable product mix led to an increase of 5% (12% at CER) in net income attributable to HUTCHMED to \$35.1 million (H1-22: \$33.6m).

The SHPL operation is large-scale, with a commercial team of about 2,300 staff managing the medical detailing and marketing of its 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 Good Manufacturing Practice-certified factory holds 74 drug product manufacturing licenses and is operated by about 550 manufacturing staff.

SXBX⁷⁴ pill: SHPL’s main product is SXBX pill, an oral vasodilator prescription therapy for coronary artery disease. SXBX pill is the second largest botanical prescription drug in this indication in China, with a national market share in the first five months of 2023 of 22.2% (first four months of 2022: 21.5%). Sales increased by 8% (16% at CER) to \$214.5 million in the first half of 2023 (H1-22: \$197.9m).

SXBX pill is protected by a formulation patent that expires in 2029, but also retains certain state protection that extends indefinitely, and is one of less than two dozen proprietary prescription drugs represented on China’s National Essential Medicines List (NEML). Inclusion on this list means that all Chinese state-owned health care institutions are required to carry it. SXBX pill is fully reimbursed in all of China.

We continue to explore divestment and equity capital market opportunities to monetize our investment in SHPL.

Dividends: Our share of SHPL’s profits are passed to the HUTCHMED Group through dividend payments. In the first six months of 2023, dividends of \$14.6 million (H1-22: \$22.7m) were paid from SHPL to the HUTCHMED Group level with aggregate dividends received by HUTCHMED since inception of over \$300 million.

Weiguo Su
 Chief Executive Officer and Chief Scientific Officer
 July 31, 2023

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 Group net cash flows excluding financing activities
- CER

Management uses such measures internally for planning and forecasting purposes and to measure the HUTCHMED 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 Group net cash flows excluding financing activities: We exclude deposits in and proceeds from short-term investments for the period, and exclude the net cash 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 excluding financing activities provides useful and meaningful information about the change in our cash resources excluding those from financing activities which may present significant period-to-period differences.

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.

Reconciliation of GAAP change in net cash generated from/(used in) operating activities to Adjusted Group net cash flows excluding financing activities:

\$'millions	H1 2023	H1 2022
Net cash generated from/(used in) operating activities	226.4	(89.9)
Net cash (used in)/generated from investing activities	(316.0)	259.7
Effect of exchange rate changes on cash and cash equivalents	(6.6)	(5.2)
Excludes: Deposits in short-term investments	835.1	578.6
Excludes: Proceeds from short-term investments	(519.6)	(854.1)
Adjusted Group net cash flows excluding financing activities	219.3	(110.9)

Reconciliation of GAAP revenues and net income attributable to HUTCHMED to CER:

\$'millions (except %)	Six Months Ended		Change Amount			Change %		
	June 30, 2023	June 30, 2022	Actual	CER	Exchange effect	Actual	CER	Exchange effect
Consolidated revenues	532.9	202.0	330.9	348.9	(18.0)	164%	173%	-9%
— Oncology/Immunology*	359.2	91.1	268.1	274.4	(6.3)	294%	301%	-7%
* Includes:								
— Products Sales	80.1	63.5	16.6	22.4	(5.8)	26%	35%	-9%
— ELUNATE®	42.0	36.0	6.0	9.1	(3.1)	16%	25%	-9%
— SULANDA®	22.6	13.6	9.0	10.7	(1.7)	66%	79%	-13%
— ORPATHYS®	15.1	13.8	1.3	2.3	(1.0)	10%	17%	-7%
— TAZVERIK®	0.4	0.1	0.3	0.3	—	560%	583%	-23%
— Other R&D services income	20.4	12.6	7.8	8.3	(0.5)	62%	66%	-4%
— Other Ventures^	173.7	110.9	62.8	74.5	(11.7)	57%	67%	-10%
^ Includes:								
— Hutchison Sinopharm	166.7	99.3	67.4	78.8	(11.4)	68%	79%	-11%
— prescription drugs								
Non-consolidated joint venture revenues								
— SHPL	235.3	212.4	22.9	39.0	(16.1)	11%	19%	-8%
— SXBX pill	214.5	197.9	16.6	32.0	(15.4)	8%	16%	-8%
Consolidated net income attributable to HUTCHMED — Other Ventures	37.2	35.4	1.8	4.2	(2.4)	5%	12%	-7%
— Consolidated entities	2.1	1.8	0.3	0.4	(0.1)	11%	19%	-8%
— Equity investees								
— SHPL	35.1	33.6	1.5	3.8	(2.3)	5%	12%	-7%

GROUP CAPITAL RESOURCES

LIQUIDITY AND CAPITAL RESOURCES

To date, we have taken a multi-source approach to fund our operations, including through cash flows generated and dividend payments from our Oncology/Immunology and Other Ventures operations, service and milestone and upfront payments from our collaboration partners, bank borrowings, investments from third parties, proceeds from our listings on various stock exchanges and follow-on offerings.

Primarily due to a recognition of \$258.7 million in partnering revenue from the upfront payment from Takeda, commercial progress achieved on our three in-house developed oncology medicines in China, as well as growth in our third-party distribution sales, we generated a net income of \$168.6 million for the six months ended June 30, 2023 (H1-22: net loss of \$162.9m).

As of June 30, 2023, we had cash and cash equivalents and short-term investments of \$856.2 million and unutilized bank facilities of \$65.3 million. As of June 30, 2023, we had \$40.1 million in bank borrowings.

Certain of our subsidiaries and joint ventures, including those registered as wholly foreign-owned enterprises in China, are required to set aside at least 10.0% of their after-tax profits to their general reserves until such reserves reach 50.0% of their registered capital. In addition, certain of our joint ventures are required to allocate certain of their after-tax profits as determined in accordance with related regulations and their respective articles of association to the reserve funds, upon approval of the board.

Profit appropriated to the reserve funds for our subsidiaries and joint ventures incorporated in the PRC was approximately \$127,000 and nil for the six months ended June 30, 2023 and 2022, respectively. In addition, as a result of PRC regulations restricting dividend distributions from such reserve funds and from a company's registered capital, our PRC subsidiaries are restricted in their ability to transfer a certain amount of their net assets to us as cash dividends, loans or advances. This restricted portion amounted to \$0.1 million as of June 30, 2023.

In addition, our non-consolidated joint venture, SHPL, held an aggregate of \$43.6 million in cash and cash equivalents and no bank borrowings as of June 30, 2023. Such cash and cash equivalents are only accessible by us through dividend payments from the joint venture. The level of dividends declared by the joint venture is subject to agreement each year between us and our joint venture partner based on the profitability and working capital needs of the joint venture.

CASH FLOW

	Six Months Ended June 30,	
	2023	2022
	(in \$'000)	
Cash Flow Data:		
Net cash generated from/(used in) operating activities	226,403	(89,859)
Net cash (used in)/generated from investing activities	(315,957)	259,706
Net cash generated from/(used in) financing activities	5,830	(74,638)
Net (decrease)/increase in cash and cash equivalents	(83,724)	95,209
Effect of exchange rate changes	(6,558)	(5,249)
Cash and cash equivalents at beginning of the period	313,278	377,542
Cash and cash equivalents at end of the period	222,996	467,502

Net Cash generated from/(used in) Operating Activities

Net cash used in operating activities was \$89.9 million for the six months ended June 30, 2022, compared to net cash generated from operating activities of \$226.4 million for the six months ended June 30, 2023. The net change of \$316.3 million was primarily attributable to the net loss attributable to HUTCHMED of \$162.9 million for the six months ended June 30, 2022 compared to net income attributable to HUTCHMED of \$168.6 million for the six months ended June 30, 2023 (which included \$258.7 million in upfront income recognized from Takeda).

Net Cash (used in)/generated from Investing Activities

Net cash generated from investing activities was \$259.7 million for the six months ended June 30, 2022, compared to net cash used in investing activities of \$316.0 million for the six months ended June 30, 2023. The net change of \$575.7 million was primarily attributable to short-term investments which had net withdrawals of \$275.5 million for the six months ended June 30, 2022 as compared to net deposits of \$315.5 million for the six months ended June 30, 2023. The net change was partially offset by a dividend of \$23.9 million received from divestment of a former equity investee during the six months ended June 30, 2023.

Net Cash generated from/(used in) Financing Activities

Net cash used in financing activities was \$74.6 million for the six months ended June 30, 2022, compared to net cash generated from financing activities of \$5.8 million for the six months ended June 30, 2023. The net change of \$80.4 million was mainly attributable to bank borrowings which had a net repayment of \$26.5 million during the six months ended June 30, 2022 as compared to net proceeds of \$22.9 million during the six months ended June 30, 2023. The net change was also attributable to a decrease in purchases of ADSs of \$39.0 million by a trustee for the settlement of equity awards of the Company which totaled \$48.1 million for the six months ended June 30, 2022 as compared to \$9.1 million for the six months ended June 30, 2023, partly offset by dividends paid to non-controlling shareholders of subsidiaries of \$9.1 million for the six months ended June 30, 2023 while there was no such dividend payment for the six months ended June 30, 2022.

LOAN FACILITIES

In October 2021, our subsidiary entered into a 10-year fixed asset loan facility agreement with Bank of China Limited for the provision of a secured credit facility in the amount of RMB754.9 million (\$105.5 million) with an annual interest rate at the 5-year China Loan Prime Rate less 0.8% (which was supplemented in June 2022). This credit facility is guaranteed by another subsidiary of the Group, and secured by the underlying leasehold land and buildings, and includes certain financial covenant requirements. As of June 30, 2023, RMB287.3 million (\$40.1 million) was utilized from the fixed asset loan facility.

In May 2022, our subsidiary entered into a 12-month revolving loan facility with HSBC in the amount of HK\$390.0 million (\$50.0 million) with an interest rate at HIBOR⁷⁵ plus 0.5% per annum. This revolving facility is guaranteed by us. The revolving loan facility expired in May 2023.

Our non-consolidated joint venture SHPL had no bank borrowings outstanding as of June 30, 2023.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table sets forth our contractual obligations as of June 30, 2023. Our purchase obligations relate to property, plant and equipment that are contracted for but not yet paid. Our lease obligations primarily comprise future aggregate minimum lease payments in respect of various factories, warehouses, offices and other assets under non-cancellable lease agreements.

	Payment Due by Period (in \$'000)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Bank borrowings	40,147	-	1,596	4,786	33,765
Interest on bank borrowings	9,231	1,365	2,716	2,508	2,642
Purchase obligations	5,039	4,687	352	-	-
Lease obligations	11,648	5,325	4,676	1,647	-
	<u>66,065</u>	<u>11,377</u>	<u>9,340</u>	<u>8,941</u>	<u>36,407</u>

SHPL

The following table sets forth the contractual obligations of our non-consolidated joint venture SHPL as of June 30, 2023. SHPL's purchase obligations comprise capital commitments for property, plant and equipment contracted for but not yet paid. SHPL's lease obligations primarily comprise future aggregate minimum lease payments in respect of various offices under non-cancellable lease agreements.

Payment Due by Period (in \$'000)

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Purchase obligations	1,168	1,168	–	–	–
Lease obligations	1,771	832	939	–	–
	2,939	2,000	939	–	–

FOREIGN EXCHANGE RISK

A substantial portion of our revenues and expenses are denominated in renminbi, and our consolidated financial statements are presented in U.S. dollars. While we do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk, any significant fluctuation in the value of renminbi may adversely affect our cash flows, results of operations and financial condition in the future.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of renminbi into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC⁷⁶. If we decide to convert renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the renminbi would have a negative effect on the U.S. dollar amounts available to us. On the other hand, if we need to convert U.S. dollars into renminbi for business purposes, e.g. capital expenditures and working capital, appreciation of the renminbi against the U.S. dollar would have a negative effect on the renminbi amounts we would receive from the conversion. In addition, for certain cash and bank balances deposited with banks in the PRC, if we decide to convert them into foreign currencies, they are subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

CREDIT RISK

Substantially all of our bank deposits are in major financial institutions, which we believe are of high credit quality. We limit the amount of credit exposure to any single financial institution. We make periodic assessments of the recoverability of trade and other receivables and amounts due from related parties. Our historical experience in collection of receivables falls within the recorded allowances, and we believe that we have made adequate provision for uncollectible receivables.

INTEREST RATE RISK

We have no significant interest-bearing assets except for bank deposits. Our exposure to changes in interest rates is mainly attributable to our bank borrowings, which bear interest at floating interest rates and expose us to cash flow interest rate risk. We have not used any interest rate swaps to hedge our exposure to interest rate risk. We have performed sensitivity analysis for the effects on our results for the period from changes in interest rates on floating rate borrowings. The sensitivity to interest rates used is based on the market forecasts available at the end of the reporting period and under the economic environments in which we operate, with other variables held constant. According to the analysis, the impact on our results of a 1.0% interest rate shift would be nil for the six months ended June 30, 2023 because the entire interest expenses incurred for the six months ended June 30, 2023 were associated with our outstanding fixed asset loan and were capitalized when the underlying property, plant and equipment were under construction.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the years presented, and we do not currently have, any material off-balance sheet arrangements.

CONTINGENT LIABILITIES

Other than as disclosed in note 11 to the interim financial statements, the Group does not have any other significant commitments or contingent liabilities.

GEARING RATIO

The gearing ratio of the Group, which was calculated by dividing total interest-bearing loans by total equity, was 5.0% as of June 30, 2023, an increase from 2.8% as of December 31, 2022. The increase was primarily attributable to the increase in interest-bearing loans.

SIGNIFICANT INVESTMENTS HELD

Except for our investment in a non-consolidated joint venture SHPL with a carrying value of \$37.7 million including details below and those as disclosed in note 7 to the interim financial statements, we did not hold any other significant investments in the equity of any other companies as of June 30, 2023.

Place of establishment and operations	Nominal Value of Registered Capital (in RMB'000)	Equity Interest Attributable to the Group	Principal activities
PRC	229,000	50%	Manufacture and distribution of prescription drug products

Our own-brand prescription drugs business under our Other Ventures is operated through SHPL. Dividends received from SHPL for the six months ended June 30, 2023 were \$14.6 million.

FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

Note 11 discloses our capital commitment as of June 30, 2023. We are building a new drug product facility in Shanghai, China, and will make additional investments in capital assets accordingly.

MATERIAL ACQUISITIONS AND DISPOSALS OF SUBSIDIARIES, ASSOCIATES AND JOINT VENTURES

During the six months ended June 30, 2023, we did not have any other material acquisitions and disposals of subsidiaries, associates and joint ventures.

PLEDGE OF ASSETS

Our 10-year fixed asset loan facility agreement with Bank of China Limited is secured by the underlying leasehold land and buildings. RMB287.3 million (\$40.1 million) was utilized from the fixed asset loan facility as of June 30, 2023.

INFLATION

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. According to the National Bureau of Statistics of China, the Consumer Price Index in China increased by 1.5%, 1.8% and flat in 2021, 2022 and the first half of 2023, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

INTERIM DIVIDEND

The Board does not recommend any interim dividend for the six months ended June 30, 2023.

OTHER INFORMATION

CORPORATE STRATEGY

The primary objective of the Company is to be a leader in the discovery, development and commercialization of targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. The strategy of the Company is to leverage the highly specialized expertise of the drug discovery division, the Oncology/Immunology operations, to develop and expand the drug candidate portfolio of the Group for the global market, building on the first-mover advantage in the development and launch of novel cancer medicines in China, and engaging partners for late-stage development and commercialization outside China. This strategy is aligned with the Company's culture of innovation and high engagement and empowerment with a strong focus on reward and recognition. The Chairman's Statement and the Operations Review contain discussions and analyses of the Group's opportunities, performance and the basis on which the Group generates or preserves value over the longer term and the basis on which the Group will execute its strategy for delivering its objectives. The Group also focuses on sustainability and delivering business solutions to support the transition to a low-carbon economy.

HUMAN RESOURCES

As at June 30, 2023, the Group employed approximately 1,990 (June 30, 2022: ~2,110) full time staff members. Staff costs during the six months ended June 30, 2023, including directors' emoluments, totaled \$104.0 million (H1-22: \$118.9 million).

The Group fully recognizes the importance of high-quality human resources in sustaining market leadership. Salary and benefits are kept at competitive levels, while individual performance is rewarded within the general framework of the salary, bonus and incentive system of the Group, which is reviewed annually. Employees are provided with a wide range of benefits that include medical coverage, provident funds and retirement plans, and long-service awards. The Group stresses the importance of staff development and provides training programs on an ongoing basis. Employees are also encouraged to play an active role in community care activities.

SUSTAINABILITY

The key sustainability mission of the Group is to create long-term value for all stakeholders by aligning its sustainability objectives to the strategic development of its businesses. The Board of Directors ("the Board") has the overall responsibility to ensure that sustainability issues are integrated into the strategy and long-term development of the Group. It provides oversight of the sustainability performance of the Group through closely monitoring key sustainability matters and performance indicators, along with trends, risks, and opportunities that may impact the business development of the Group. Supported by the Sustainability Committee, senior management, and the Sustainability Working Group, the Board oversees the management approach to sustainability matters and the formulation of sustainability strategies.

A standalone Sustainability Report of the Company for 2022 was published alongside the 2022 Annual Report in April 2023 and included further information on the Group's sustainability initiatives and their performances. It further discussed the abovementioned sustainability mission and strategies, management approach, progress, material quantitative data, as well as policies and key initiatives of the Group. Over the course of 2023, the Group continues to engage its stakeholders to identify areas for improvement in these sustainability fronts.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

During the period from January 1, 2023 to June 30, 2023, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the listed securities of the Company.

COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

The Company strives to attain and maintain high standards of corporate governance best suited to the needs and interests of the Company and its subsidiaries as it believes that effective corporate governance framework is fundamental to promoting and safeguarding interests of shareholders and other stakeholders and enhancing shareholder value. Accordingly, the Company has adopted and applied corporate governance principles and practices that emphasize a quality Board, effective

risk management and internal control systems, stringent disclosure practices, transparency and accountability as well as effective communication and engagement with shareholders and other stakeholders. It is, in addition, committed to continuously enhancing these standards and practices and inculcating a robust culture of compliance and ethical governance underlying the business operations and practices across the Group.

The Company has complied throughout the six months ended June 30, 2023 with all applicable code provisions of the Hong Kong Corporate Governance Code contained in Appendix 14 of the Rules Governing the Listing of Securities on HKEX (the “Hong Kong Listing Rules”).

COMPLIANCE WITH THE SHARE DEALINGS CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS

The Board has adopted the Code on Dealings in Shares which is on terms no less exacting than the required standard set out in the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 of the Hong Kong Listing Rules as the protocol regulating Directors’ dealings in securities of the Company. In response to specific enquiries made, all Directors have confirmed that they have complied with the required standards set out in such code regarding their securities transactions throughout their tenure during the six months ended June 30, 2023.

USE OF NET PROCEEDS

On June 30, 2021, the Company issued 104,000,000 new ordinary shares for total gross proceeds of approximately \$534.7 million from the listing of the Company’s ordinary shares on HKEX.

On July 15, 2021, the over-allotment option was fully exercised and the Company issued an aggregate of 15,600,000 ordinary shares for total gross proceeds of approximately \$80.2 million.

The intended use of total net proceeds of approximately \$585.2 million from the offering and the over-allotment option for the purposes and in the amounts (adjusted on pro rata basis based on the actual net proceeds) as disclosed in the prospectus of the Company dated June 18, 2021 is as below:

Use of Proceeds	Percentage of Total Net Proceeds	Approximate Amount	Actual Usage up to June 30, 2023	Unutilized Net Proceeds as of June 30, 2023	Expected Timeline for Utilization of Proceeds (note)
	(%)	(\$'millions)	(\$'millions)	(\$'millions)	
Advance our late-stage clinical programs for savolitinib, surufatinib, fruquintinib, amdzalisib and soveplenib through registration trials and potential NDA submissions	50%	292.7	292.7	-	Fully utilized
Support further proof-of-concept studies and fund the continued expansion of our product portfolio in cancer and immunological diseases through internal research, including the development cost of early-clinical and preclinical-stage pipeline drug candidates	10%	58.5	58.5	-	Fully utilized
Further strengthen our integrated capabilities across commercialization, clinical and regulatory and manufacturing	20%	117.1	102.8	14.3	2023
Fund potential global business development and strategic acquisition opportunities to complement our internal research and development activities and enhance our current drug candidate pipeline	15%	87.8	68.8	19.0	2023
Working capital, expanding internal capabilities globally and in China and general corporate purposes	5%	29.1	29.1	-	Fully utilized
	100%	585.2	551.9	33.3	

Note: There was no change in the intended use of net proceeds as previously disclosed, and the Company plans to gradually utilize the remaining net proceeds in accordance with such intended purposes depending on actual market conditions and business needs, which is expected to be substantially utilized by the end of year 2023.

REVIEW OF INTERIM UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The interim unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2023 have been reviewed by the auditor of the Company, PricewaterhouseCoopers, in accordance with Hong Kong Standard on Review Engagements 2410 – “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants for the Hong Kong filing. The interim unaudited condensed consolidated financial statements of the Group for the six months ended June 30, 2023 have also been reviewed by the Audit Committee of the Company.

IMPORTANT EVENTS AFTER THE REPORTING DATE

Save as disclosed above, no important events affecting the Company occurred since June 30, 2023 and up to the date of this announcement.

PUBLICATION OF INTERIM RESULTS AND INTERIM REPORT

This interim results announcement is published on the websites of HKEX (www.hkexnews.hk), the U.S. Securities and Exchange Commission (www.sec.gov/edgar), the London Stock Exchange (www.londonstockexchange.com) and the Company (www.hutch-med.com). The interim report of the Group for the six months ended June 30, 2023 will be published on the websites of HKEX and the Company, and dispatched to the Company’s shareholders in due course.

REFERENCES & ABBREVIATIONS

¹ Takeda = Takeda Pharmaceuticals International AG.

² NDA = New Drug Application.

³ FDA = Food and Drug Administration.

⁴ PDUFA = U.S. Prescription Drug User Fee Act.

⁵ MAA = Marketing Authorization Application.

⁶ EMA = European Medicines Agency.

⁷ CRC = Colorectal cancer.

⁸ NRDL = National Reimbursement Drug List.

⁹ IHCC = Intrahepatic cholangiocarcinoma.

¹⁰ SHP2 = Src homology-2 domain-containing protein tyrosine phosphatase-2.

¹¹ CER = Constant exchange rate. We also report changes in performance at 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.

¹² R&D = Research and development.

¹³ SG&A Expenses = selling, general and administrative expenses.

¹⁴ AACR = American Association for Cancer Research.

¹⁵ ASCO = American Society of Clinical Oncology.

¹⁶ ASCO GI = ASCO (American Society of Clinical Oncology) Gastrointestinal Cancers Symposium.

¹⁷ EHA = European Hematology Association.

¹⁸ ICML = International Conference on Malignant Lymphoma.

¹⁹ In-market sales = total sales to third parties provided by Eli Lilly (ELUNATE[®]), AstraZeneca (ORPATHYS[®]) and HUTCHMED (ELUNATE[®], SULANDA[®], ORPATHYS[®] and TAZVERIK[®]).

²⁰ Lilly = Eli Lilly and Company.

²¹ NMPA = National Medical Products Administration.

²² PMDA = Pharmaceuticals and Medical Devices Agency.

²³ NSCLC = Non-small cell lung cancer.

²⁴ MET = Mesenchymal epithelial transition factor.

²⁵ EGFR = Epidermal growth factor receptor.

²⁶ PRCC = Papillary renal cell carcinoma.

²⁷ VEGFR = Vascular endothelial growth factor receptor.

²⁸ PD-1 = Programmed cell death protein-1.

²⁹ RCC = Renal cell carcinoma.

³⁰ FGFR = Fibroblast growth factor receptor.

³¹ CSF-1R = Colony-stimulating factor 1 receptor.

³² Syk = Spleen tyrosine kinase.

³³ AIHA = Autoimmune hemolytic anemia.

³⁴ ITP = Immune thrombocytopenia purpura.

³⁵ PI3K δ = Phosphoinositide 3-kinase delta.

- ³⁶ Ipsen = Ipsen SA, parent of Epizyme Inc.
- ³⁷ Epizyme = Epizyme Inc., a wholly owned subsidiary of Ipsen SA.
- ³⁸ IDH = Isocitrate dehydrogenase.
- ³⁹ BTK = Bruton's tyrosine kinase.
- ⁴⁰ ERK = Extracellular signal-regulated kinase.
- ⁴¹ MAPK pathway = RAS-RAF-MEK-ERK signaling cascade.
- ⁴² CDE = Center for Drug Evaluation
- ⁴³ SHPL = Shanghai Hutchison Pharmaceuticals Limited.
- ⁴⁴ GAAP = Generally Accepted Accounting Principles.
- ⁴⁵ ADS = American depositary share.
- ⁴⁶ HKEX = The Main Board of The Stock Exchange of Hong Kong Limited.
- ⁴⁷ NHTA = China National Healthcare Security Administration.
- ⁴⁸ NET = Neuroendocrine tumor.
- ⁴⁹ CSCO = Chinese Society of Clinical Oncology.
- ⁵⁰ TKI = Tyrosine kinase inhibitor.
- ⁵¹ EGFRm+ = Epidermal growth factor receptor mutated.
- ⁵² OS = Overall survival.
- ⁵³ ORR = Objective response rate.
- ⁵⁴ JSMO = Japanese Society of Medical Oncology.
- ⁵⁵ TN = Triple negative.
- ⁵⁶ HR+ = Hormone receptor positive.
- ⁵⁷ Her2- = Human epidermal growth factor receptor 2 negative.
- ⁵⁸ MSS = Microsatellite stable.
- ⁵⁹ PFS = Progression free survival.
- ⁶⁰ DCR = Disease control rate.
- ⁶¹ DoR = Duration of response.
- ⁶² epNET = extra-pancreatic neuroendocrine tumor.
- ⁶³ pNET = pancreatic neuroendocrine tumor.
- ⁶⁴ NEC = Neuroendocrine carcinoma.
- ⁶⁵ NEN = Neuroendocrine neoplasms.
- ⁶⁶ SCLC = Small cell lung cancer.
- ⁶⁷ ASH = American Society of Hematology.
- ⁶⁸ NHL = Non-Hodgkin's lymphoma.
- ⁶⁹ CLL = Chronic lymphocytic leukemia.
- ⁷⁰ SLL = Small lymphocytic lymphoma.
- ⁷¹ API = Active pharmaceutical ingredient.
- ⁷² Hutchison Sinopharm = Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited.
- ⁷³ Luye = Luye Pharma Hong Kong Ltd.
- ⁷⁴ SXBX = She Xiang Bao Xin.
- ⁷⁵ HIBOR = Hong Kong Interbank Offered Rate.
- ⁷⁶ PBOC = People's Bank of China.

INTERIM UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

HUTCHMED (CHINA) LIMITED CONDENSED CONSOLIDATED BALANCE SHEETS (IN US\$'000, EXCEPT SHARE DATA)

	Note	June 30, 2023	December 31, 2022
Assets		(Unaudited)	
Current assets			
Cash and cash equivalents	3	222,996	313,278
Short-term investments	3	633,172	317,718
Accounts receivable	4	129,203	97,988
Other receivables, prepayments and deposits	5	29,280	53,216
Amount due from a related party	15(ii)	21,959	998
Inventories	6	53,875	56,690
Total current assets		1,090,485	839,888
Property, plant and equipment		96,829	75,947
Investments in equity investees	7	37,740	73,777
Amount due from a related party, non-current portion	15(ii)	32,896	—
Other non-current assets		39,547	39,833
Total assets		1,297,497	1,029,445
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	8	54,575	71,115
Other payables, accruals and advance receipts	9	227,212	264,621
Deferred revenue	13	52,264	13,347
Other current liabilities		6,812	4,820
Total current liabilities		340,863	353,903
Long-term bank borrowings	10	40,147	18,104
Deferred revenue, non-current portion	13	97,176	190
Other non-current liabilities		19,294	20,378
Total liabilities		497,480	392,575
Commitments and contingencies	11		
Company's shareholders' equity			
Ordinary shares; \$0.10 par value; 1,500,000,000 shares authorized; 866,161,450 and 864,775,340 shares issued at June 30, 2023 and December 31, 2022 respectively		86,616	86,478
Additional paid-in capital		1,506,280	1,497,273
Accumulated losses		(803,057)	(971,481)
Accumulated other comprehensive loss		(7,800)	(1,903)
Total Company's shareholders' equity		782,039	610,367
Non-controlling interests		17,978	26,503
Total shareholders' equity		800,017	636,870
Total liabilities and shareholders' equity		1,297,497	1,029,445

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

HUTCHMED (CHINA) LIMITED
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED, IN US\$'000, EXCEPT SHARE AND PER SHARE DATA)

	Note	Six Months Ended June 30,	
		2023	2022
Revenues			
Goods —third parties		209,247	136,932
—related parties	15(i)	4,252	1,638
Services —commercialization—third parties		25,359	21,594
—collaboration research and development			
—third parties		28,718	12,335
—research and development—related party	15(i)	246	263
Other collaboration revenue			
—royalties—third parties		14,982	14,331
—licensing—third parties		250,070	14,954
Total revenues	13	532,874	202,047
Operating expenses			
Costs of goods—third parties		(182,380)	(115,567)
Costs of goods—related parties		(2,536)	(1,198)
Costs of services—commercialization —third parties		(23,408)	(20,553)
Research and development expenses	14	(144,633)	(181,741)
Selling expenses		(26,423)	(22,221)
Administrative expenses		(41,840)	(57,521)
Total operating expenses		(421,220)	(398,801)
		111,654	(196,754)
Other income/(expense), net		25,434	(3,882)
Income/(loss) before income taxes and equity in earnings of equity investees		137,088	(200,636)
Income tax (expense)/benefit	16	(2,730)	4,215
Equity in earnings of equity investees, net of tax	7	35,110	33,549
Net income/(loss)		169,468	(162,872)
Less: Net (income)/loss attributable to non-controlling interests		(917)	11
Net income/(loss) attributable to the Company		168,551	(162,861)
Earnings/(losses) per share attributable to the Company (US\$ per share)			
—basic	17	0.20	(0.19)
—diluted	17	0.19	(0.19)
Number of shares used in per share calculation			
—basic	17	846,928,863	849,283,553
—diluted	17	866,990,610	849,283,553

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

HUTCHMED (CHINA) LIMITED
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE
INCOME/(LOSS)
(UNAUDITED, IN US\$'000)

	Six Months Ended June 30,	
	2023	2022
Net income/(loss)	169,468	(162,872)
Other comprehensive loss		
Foreign currency translation loss	(6,245)	(4,175)
Total comprehensive income/(loss)	163,223	(167,047)
Less: Comprehensive (income)/loss attributable to non-controlling interests	(573)	496
Total comprehensive income/(loss) attributable to the Company	162,650	(166,551)

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

HUTCHMED (CHINA) 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, 2022	864,531	86,453	1,505,196	(610,328)	5,572	986,893	52,621	1,039,514
Net loss	—	—	—	(162,861)	—	(162,861)	(11)	(162,872)
Issuances in relation to share option exercises	44	4	30	—	—	34	—	34
Share-based compensation								
Share options	—	—	3,732	—	—	3,732	9	3,741
Long-term incentive plan ("LTIP")	—	—	23,704	—	—	23,704	(13)	23,691
	—	—	27,436	—	—	27,436	(4)	27,432
LTIP—treasury shares acquired and held by Trustee	—	—	(48,084)	—	—	(48,084)	—	(48,084)
Foreign currency translation adjustments	—	—	—	—	(3,690)	(3,690)	(485)	(4,175)
As at June 30, 2022	864,575	86,457	1,484,578	(773,189)	1,882	799,728	52,121	851,849
As at January 1, 2023	864,775	86,478	1,497,273	(971,481)	(1,903)	610,367	26,503	636,870
Net income	—	—	—	168,551	—	168,551	917	169,468
Issuances in relation to share option exercises	1,386	138	920	—	—	1,058	—	1,058
Share-based compensation								
Share options	—	—	3,236	—	—	3,236	3	3,239
LTIP	—	—	13,844	—	—	13,844	(33)	13,811
	—	—	17,080	—	—	17,080	(30)	17,050
LTIP—treasury shares acquired and held by Trustee	—	—	(9,071)	—	—	(9,071)	—	(9,071)
Dividends declared to non- controlling shareholders of subsidiaries	—	—	—	—	—	—	(9,068)	(9,068)
Transfer between reserves	—	—	127	(127)	—	—	—	—
Divestment of an equity investee	—	—	(49)	—	4	(45)	—	(45)
Foreign currency translation adjustments	—	—	—	—	(5,901)	(5,901)	(344)	(6,245)
As at June 30, 2023	866,161	86,616	1,506,280	(803,057)	(7,800)	782,039	17,978	800,017

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

HUTCHMED (CHINA) LIMITED
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED, IN US\$'000)

	Note	Six Months Ended June 30,	
		2023	2022
Net cash generated from/(used in) operating activities	19	226,403	(89,859)
Investing activities			
Purchases of property, plant and equipment		(24,359)	(15,754)
Deposits in short-term investments		(835,092)	(578,602)
Proceeds from short-term investments		519,638	854,062
Dividend received from divestment of Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited		23,856	—
Net cash (used in)/ generated from investing activities		(315,957)	259,706
Financing activities			
Proceeds from issuances of ordinary shares		1,058	34
Purchases of treasury shares	12(ii)	(9,071)	(48,084)
Dividends paid to non-controlling shareholders of subsidiaries	15(iii)	(9,068)	—
Proceeds from bank borrowings		22,911	418
Repayment of bank borrowings		—	(26,923)
Payment of issuance costs		—	(83)
Net cash generated from/(used in) financing activities		5,830	(74,638)
Net (decrease)/increase in cash and cash equivalents		(83,724)	95,209
Effect of exchange rate changes on cash and cash equivalents		(6,558)	(5,249)
		(90,282)	89,960
Cash and cash equivalents			
Cash and cash equivalents at beginning of period		313,278	377,542
Cash and cash equivalents at end of period		222,996	467,502

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

HUTCHMED (CHINA) LIMITED

NOTES TO THE INTERIM UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Business

HUTCHMED (China) Limited (the “Company”) and its subsidiaries (together the “Group”) are principally engaged in researching, developing, manufacturing and marketing pharmaceutical products. The Group and its equity investee 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, including Hong Kong and Macau. In addition, the Group has established international operations in the United States of America (the “U.S.”) and Europe.

The Company’s ordinary shares are listed on the Main Board of The Stock Exchange of Hong Kong Limited and the AIM market of the London Stock Exchange, and its American depository shares (“ADS”) are traded on the Nasdaq Global Select Market.

Liquidity

As at June 30, 2023, the Group had accumulated losses of US\$803,057,000 primarily due to its spending in drug research and development 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, 2023, the Group had cash and cash equivalents of US\$222,996,000, short-term investments of US\$633,172,000 and unutilized bank borrowing facilities of US\$65,343,000. Short-term investments comprised of bank deposits maturing over three months.

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 from the issuance date of the interim unaudited condensed consolidated financial statements (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. 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.

Recent Accounting Pronouncements

Amendments that have been issued by the Financial Accounting Standards Board or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Group’s condensed consolidated financial statements.

3. Cash and Cash Equivalents and Short-term Investments

	June 30, 2023	December 31, 2022
(in US\$'000)		
Cash and Cash Equivalents		
Cash at bank and on hand	71,244	178,326
Bank deposits maturing in three months or less	151,752	134,952
	222,996	313,278
Short-term Investments		
Bank deposits maturing over three months (note)	633,172	317,718
	856,168	630,996

Note: The maturities for short-term investments ranged from 91 to 187 days and 91 to 99 days for the six months ended June 30, 2023 and the year ended December 31, 2022 respectively.

Certain cash and bank balances denominated in Renminbi (“RMB”), U.S. dollar (“US\$”) and UK Pound Sterling (“£”) 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.

Cash and cash equivalents and short-term investments were denominated in the following currencies:

	June 30, 2023	December 31, 2022
(in US\$'000)		
US\$	822,603	533,173
RMB	21,933	79,319
Hong Kong dollar (“HK\$”)	9,872	16,721
£	1,417	1,370
Others	343	413
	856,168	630,996

4. Accounts Receivable

Accounts receivable from contracts with customers consisted of the following:

	June 30, 2023	December 31, 2022
(in US\$'000)		
Accounts receivable—third parties	127,180	94,531
Accounts receivable—related parties (Note 15(ii))	2,212	3,517
Allowance for credit losses	(189)	(60)
Accounts receivable, net	129,203	97,988

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.

An aging analysis for accounts receivable—third parties based on the relevant invoice dates is as follows:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Not later than 3 months	109,809	84,007
Between 3 months to 6 months	14,073	7,478
Between 6 months to 1 year	2,088	1,947
Later than 1 year	1,210	1,099
Accounts receivable—third parties	<u>127,180</u>	<u>94,531</u>

Movements on the allowance for credit losses:

	2023	2022
	(in US\$'000)	
As at January 1	60	20
Increase in allowance for credit losses	150	119
Decrease in allowance due to subsequent collection	(17)	(14)
Exchange difference	(4)	(4)
As at June 30	<u>189</u>	<u>121</u>

5. Other Receivables, Prepayments and Deposits

Other receivables, prepayments and deposits consisted of the following:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Prepayments	12,053	22,329
Value-added tax receivables	7,046	1,491
Interest receivables	5,379	807
Dividend receivables	2,527	26,246
Deposits	1,205	1,214
Others	1,070	1,129
	<u>29,280</u>	<u>53,216</u>

No allowance for credit losses has been made for other receivables, prepayments and deposits for the six months ended June 30, 2023 and year ended December 31, 2022.

6. Inventories

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

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Raw materials	27,231	27,392
Finished goods	26,644	29,298
	<u>53,875</u>	<u>56,690</u>

7. Investments in Equity Investees

Investments in equity investees consisted of the following:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Shanghai Hutchison Pharmaceuticals Limited ("SHPL")	37,740	73,461
Other (note)	—	316
	<u>37,740</u>	<u>73,777</u>

Note: On April 13, 2023, the Group completed a transaction to sell its entire investment in a former equity investee to a third party.

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

Summarized financial information for the equity investee, SHPL, is as follows:

(i) Summarized balance sheets

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Current assets	228,185	214,267
Non-current assets	74,950	80,062
Current liabilities	(163,222)	(147,952)
Non-current liabilities	(69,791)	(4,944)
Net assets	<u>70,122</u>	<u>141,433</u>

(ii) Summarized statements of operations

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Revenue	235,271	212,413
Gross profit	175,750	165,208
Interest income	438	623
Finance cost (note (a))	(1,022)	—
Income before taxation	84,064	78,472
Income tax expense (note (b))	(13,840)	(11,209)
Net income (note (c))	<u>70,224</u>	<u>67,263</u>

Notes:

- (a) On January 31, 2023, SHPL declared dividends of US\$146,974,000. Finance cost is from the accretion of the US\$3,654,000 discount recorded on the dividends payable.
- (b) The main entity within SHPL group has been granted the High and New Technology Enterprise ("HNTE") status (the latest renewal of this status covered the years from 2020 to 2022). This entity was eligible to use a preferential income tax rate of 15% for the year ended December 31, 2022 on this basis. The entity is in the process of applying to renew the HNTE status for another three years. Management considers that the renewal of HNTE status will be granted and the preferential income tax rate of 15% continues to be applicable for the six months ended June 30, 2023.

(c) Net income is before elimination of unrealized profits on transactions with the Group. The amounts eliminated were approximately US\$2,000 and US\$80,000 for the six months ended June 30, 2023 and 2022 respectively.

(iii) Reconciliation of summarized financial information

Reconciliation of the summarized financial information presented to the carrying amount of investment in SHPL is as follows:

	2023	2022
	(in US\$'000)	
Opening net assets as at January 1	141,433	145,741
Net income	70,224	67,263
Dividends declared	(146,974)	(45,385)
Discount on dividends payable	3,654	—
Other comprehensive income/(loss)	1,785	(8,544)
Closing net assets as at June 30	70,122	159,075
Group's share of net assets	35,061	79,538
Goodwill	2,795	3,000
Elimination of unrealized profits on sales to SHPL	(116)	—
Carrying amount of investments as at June 30	37,740	82,538

SHPL had the following capital commitments:

	June 30, 2023
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	1,168

8. Accounts Payable

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Accounts payable	54,575	71,115

Substantially all accounts payable are denominated in RMB, EUR 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.

An aging analysis based on the relevant invoice dates is as follows:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Not later than 3 months	48,284	60,553
Between 3 months to 6 months	2,765	7,216
Between 6 months to 1 year	2,346	2,137
Later than 1 year	1,180	1,209
	54,575	71,115

9. Other Payables, Accruals and Advance Receipts

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

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Accrued research and development expenses	140,158	156,134
Accrued salaries and benefits	27,225	42,442
Accrued capital expenditures	21,429	21,390
Accrued administrative and other general expenses	14,090	14,491
Accrued selling and marketing expenses	10,448	11,564
Deposits	3,172	3,616
Amounts due to related parties (Note 15(ii))	1,957	2,101
Deferred government grants	689	673
Others	8,044	12,210
	227,212	264,621

10. Bank Borrowings

Bank borrowings consisted of the following:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Non-current	40,147	18,104

The weighted average interest rate for outstanding bank borrowings for the six months ended June 30, 2023 and year ended December 31, 2022 was 3.51% per annum and 1.73% per annum respectively. The carrying amounts of the Group's outstanding bank borrowings as at June 30, 2023 and December 31, 2022 were denominated in RMB.

(i) 1-year revolving loan facility

In May 2022, the Group through its subsidiary, entered into a 1-year revolving loan facility with the bank in the amount of HK\$390,000,000 (US\$50,000,000) with an interest rate at Hong Kong Interbank Offered Rate plus 0.5% per annum. This credit facility was guaranteed by the Company and expired in May 2023.

(ii) 10-year fixed asset loan facility

In October 2021, a subsidiary entered into a 10-year fixed asset loan facility agreement with a bank for the provision of a secured credit facility in the amount of RMB754,880,000 (US\$105,490,000) with an annual interest rate at the 5-year China Loan Prime Rate less 0.8% (which was supplemented in June 2022) and interest payments commencing upon completion of the underlying construction in progress. This credit facility is guaranteed by the immediate holding company of the subsidiary and secured by the underlying leasehold land and buildings. As at June 30, 2023 and December 31, 2022, RMB287,287,000 (US\$40,147,000) and RMB126,083,000 (US\$18,104,000) were utilized from the fixed asset loan facility respectively, of which RMB4,708,000 (US\$658,000) and RMB769,000 (US\$110,000) were related to capitalized interest respectively.

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

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Between 1 to 3 years	1,596	360
Between 3 to 4 years	2,127	839
Between 4 to 5 years	2,659	1,079
Later than 5 years	33,765	15,826
	40,147	18,104

As at June 30, 2023, the Group had unutilized bank borrowing facilities of US\$65,343,000.

11. Commitments and Contingencies

The Group had the following capital commitments:

	June 30, 2023
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	5,039

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

12. 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 (as amended on April 27, 2020) (the "Hutchmed Share Option Scheme"). Pursuant to the Hutchmed 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, 2023, the aggregate number of shares issuable under the Hutchmed Share Option Scheme was 47,044,598 ordinary shares and the aggregate number of shares issuable under the prior share option scheme which expired in 2016 was 211,320 ordinary shares. The Company will issue new shares to satisfy share option exercises. Additionally, the number of shares authorized but unissued was 633,838,550 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.

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

	Number of share options	Weighted average exercise price in US\$ per share	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in US\$'000)
Outstanding at January 1, 2022	37,190,590	4.88	7.04	82,377
Granted (note)	7,680,820	2.26		
Exercised	(244,490)	1.98		
Cancelled	(3,849,905)	5.19		
Expired	(1,255,620)	5.66		
Outstanding at December 31, 2022	39,521,395	4.34	6.55	11,525
Granted	1,221,900	2.50		
Exercised	(1,386,110)	1.92		
Cancelled	(2,742,340)	4.68		
Expired	(1,893,370)	5.55		
Outstanding at June 30, 2023	34,721,475	4.27	6.21	1,541
Vested and exercisable at December 31, 2022	21,113,285	4.57	4.80	6,288
Vested and exercisable at June 30, 2023	21,976,870	4.58	4.97	591

Note: Includes 861,220 share options (represented by 172,244 ADS) granted to an executive director in May 2022 where the number of share options exercisable is subject to a performance target based on a market condition covering the 3-year period from 2022 to 2024 which has been reflected in estimating the grant date fair value. The grant date fair value of such awards is US\$0.24 per share using the Polynomial model. Vesting of such award will occur in March 2025 if the performance target based on a market condition is met.

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:

	Six Months Ended June 30, 2023	Year Ended December 31, 2022
Weighted average grant date fair value of share options (in US\$ per share)	1.14	0.85
Significant inputs into the valuation model (weighted average):		
Exercise price (in US\$ per share)	2.50	2.26
Share price at effective date of grant (in US\$ per share)	2.50	2.22
Expected volatility (note (a))	53.3%	46.7%
Risk-free interest rate (note (b))	3.69%	2.98%
Contractual life of share options (in years)	10	10
Expected dividend yield (note (c))	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 reference the U.S. Treasury yield curves because the Company's ADS are currently listed on the NASDAQ and denominated in US\$.
- (c) The Company has not declared or paid any dividends and does not currently expect to do so prior to the exercise of the granted share options, 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 Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Cash received from share option exercises	1,058	34
Total intrinsic value of share option exercises	1,898	57

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,	
	2023	2022
	(in US\$'000)	
Research and development expenses	1,664	2,795
Selling and administrative expenses	1,522	871
Cost of revenues	53	75
	3,239	3,741

As at June 30 2023, the total unrecognized compensation cost was US\$8,107,000, and will be recognized on a graded vesting approach over the weighted average remaining service period of 2.50 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, financings, revenues, net income/(loss) after taxes and the achievement of clinical and regulatory, business development and manufacturing 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. Based on the actual achievement of performance target, the amount previously recorded in the liability will be adjusted through share-based compensation expense.

Granted awards in 2022 and 2023 under the LTIP are as follows:

Grant date	Maximum cash amount (in US\$ millions)	Covered financial years	Performance target determination date
May 23, 2022	60.4	2022	note (a)
September 13, 2022	3.8	2022	note (a)
September 13, 2022	1.7	note (b)	note (b)
June 5, 2023	54.9	2023	note (a)

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 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.
- (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.

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 Company using funds provided by the Company. 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 ordinary share equivalent) held by the Trustee were as follows:

	Number of treasury shares	Cost (in US\$'000)
As at January 1, 2022	8,139,175	40,014
Purchased	14,028,465	48,084
Vested	(2,566,265)	(12,034)
As at December 31, 2022	19,601,375	76,064
Purchased	2,725,515	9,071
Vested	(4,480,895)	(17,267)
As at June 30, 2023	17,845,995	67,868

For the six months ended June 30, 2023 and 2022, US\$5,041,000 and US\$8,397,000 of the LTIP awards were forfeited respectively based on the determined or estimated monetary amount as at the forfeiture date.

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

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Research and development expenses	5,700	7,196
Selling and administrative expenses	4,614	4,228
Cost of revenues	237	213
	10,551	11,637
Recorded with a corresponding credit to:		
Liability	1,303	3,297
Additional paid-in capital	9,248	8,340
	10,551	11,637

For the six months ended June 30, 2023 and 2022, US\$4,563,000 and US\$15,351,000 were reclassified from liability to additional paid-in capital respectively upon LTIP awards reaching the determination date. As at June 30, 2023 and December 31, 2022, US\$441,000 and US\$3,701,000 were recorded as liabilities respectively for LTIP awards prior to the determination date.

As at June 30, 2023, the total unrecognized compensation cost was approximately US\$38,153,000, which considers expected performance targets and the amounts expected to vest, and will be recognized over the requisite periods.

13. Revenues

The following table presents revenue disaggregated by type:

	Six Months Ended June 30, 2023		
	Oncology/Immunology	Other Ventures	Total
	(in US\$'000)		
Goods—Marketed Products	39,808	—	39,808
Goods—Distribution	—	173,691	173,691
Services—Commercialization—Marketed Products	25,359	—	25,359
—Collaboration Research and Development	28,718	—	28,718
—Research and Development	246	—	246
Royalties	14,982	—	14,982
Licensing	250,070	—	250,070
	<u>359,183</u>	<u>173,691</u>	<u>532,874</u>
Third parties	358,937	169,439	528,376
Related parties (Note 15(i))	246	4,252	4,498
	<u>359,183</u>	<u>173,691</u>	<u>532,874</u>
	Six Months Ended June 30, 2022		
	Oncology/Immunology	Other Ventures	Total
	(in US\$'000)		
Goods—Marketed Products	27,592	—	27,592
Goods—Distribution	—	110,978	110,978
Services—Commercialization—Marketed Products	21,594	—	21,594
—Collaboration Research and Development	12,335	—	12,335
—Research and Development	263	—	263
Royalties	14,331	—	14,331
Licensing	14,954	—	14,954
	<u>91,069</u>	<u>110,978</u>	<u>202,047</u>
Third parties	90,806	109,340	200,146
Related parties (Note 15(i))	263	1,638	1,901
	<u>91,069</u>	<u>110,978</u>	<u>202,047</u>

The following table presents liability balances from contracts with customers:

	June 30,	December 31,
	2023	2022
	(in US\$'000)	
Deferred revenue		
Current—Oncology/Immunology segment (note (a))	51,232	11,817
Current—Other Ventures segment (note (b))	1,032	1,530
	52,264	13,347
Non-current—Oncology/Immunology segment (note (a))	97,176	190
Total deferred revenue (note (c) and (d))	<u>149,440</u>	<u>13,537</u>

Notes:

- (a) Oncology/Immunology segment deferred revenue relates to invoiced amounts for unamortized upfront and milestone payments, royalties where the customer has not yet completed the in-market sale and advance consideration received for cost reimbursements which are attributed to research and development services that have not yet been rendered as at the reporting date.

- (b) Other Ventures segment deferred revenue relates to payments in advance from customers for goods that have not been transferred and services that have not been rendered to the customer as at the reporting date.
- (c) Estimated deferred revenue to be recognized over time as from the date indicated is as follows:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Not later than 1 year	52,264	13,347
Between 1 to 2 years	33,756	150
Between 2 to 3 years	36,355	40
Between 3 to 4 years	20,292	—
Later than 4 years	6,773	—
	149,440	13,537

- (d) As at January 1, 2023, deferred revenue was US\$13.5 million, of which US\$8.5 million was recognized during the six months ended June 30, 2023.

License and collaboration agreement with Takeda Pharmaceutical

On January 23, 2023, the Group and Takeda Pharmaceuticals International AG entered into an exclusive out-licensing agreement (the “Takeda Agreement”) to further the global development, commercialization and manufacturing of Fruquintinib in territories outside of Mainland China, Hong Kong and Macau (the “Territory”). Under the terms of the Takeda Agreement, the Group is entitled to receive a series of payments up to US\$1.13 billion, including upfront, regulatory, development and commercial sales milestone payments, plus royalties on net sales in the Territory. During the six months ended June 30, 2023, the Group has received \$400 million upfront payment.

The Takeda Agreement has the following material performance obligations: (1) the licenses for the development and commercialization of Fruquintinib in the Territory and the manufacture of Fruquintinib for use in the Territory, (2) services for research and development of ongoing clinical trials, regulatory submissions and manufacturing technology transfer and (3) manufacturing supply.

The transaction price for these performance obligations includes the upfront payment, service cost reimbursements, milestone payments and sales-based royalties. Milestone payments were not included in the transaction price until it becomes probable that a significant reversal of revenue would not occur, which is generally when the criteria to receive the milestone are achieved. Manufacturing sales are variable consideration and were not included in the transaction price at inception as regulatory approval had not been achieved.

The allocation of the transaction price to each performance obligation was based on the relative standalone selling price of each performance obligation determined at the inception of the contract. Based on this estimation, proportionate amounts of transaction price to be allocated to the licenses, and other performance obligations were 62% and 38% respectively.

Control of the licenses to Fruquintinib was transferred at the inception date of the agreement and consequently, amounts allocated to this performance obligation were recognized at inception. Conversely, services are performed over the term of the Takeda Agreement and amounts allocated are recognized over time using a percentage-of-completion method and manufacturing supply is recognized at a point in time when the control of the goods is transferred. Royalties are recognized as future sales occur as they meet the requirements for the sales-usage based royalty exception.

Revenue recognized under the Takeda Agreement is as follows:

	Six Months Ended June 30, 2023
	(in US\$'000)
Licensing—from upfront payment	250,070
Services—collaboration research and development—from deferred upfront payment	8,615
Services—collaboration research and development—cost reimbursements	10,372
	<u>269,057</u>

14. Research and Development Expenses

Research and development expenses are summarized as follows:

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Clinical trial related costs	94,909	122,513
Personnel compensation and related costs	45,410	52,738
Other research and development expenses	4,314	6,490
	<u>144,633</u>	<u>181,741</u>

The Group has entered into multiple collaborative arrangements under ASC 808 to evaluate the combination of the Group's drug compounds with the collaboration partners' drug compounds. For the six months ended June 30, 2023 and 2022, the Group has incurred research and development expenses of US\$8,067,000 and US\$6,818,000 respectively, related to such collaborative arrangements.

15. 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 Ended June 30,	
	2023	2022
	(in US\$'000)	
Sales to:		
Indirect subsidiaries of CK Hutchison Holdings Limited ("CK Hutchison")	1,008	1,638
An equity investee	3,244	—
	<u>4,252</u>	<u>1,638</u>
Revenue from research and development services from:		
An equity investee	246	263
Purchases from:		
An equity investee	1,911	2,225
Rendering of marketing services from:		
Indirect subsidiaries of CK Hutchison	59	77
An equity investee	—	62
	<u>59</u>	<u>139</u>
Rendering of management services from:		
An indirect subsidiary of CK Hutchison	498	490

(ii) Balances with related parties included in:

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Accounts receivable—related parties		
Indirect subsidiaries of CK Hutchison (note (a))	773	1,319
An equity investee (note (a))	1,439	2,198
	<u>2,212</u>	<u>3,517</u>
Amount due from a related party		
An equity investee (note (a) and (b))	21,959	998
Amount due from a related party, non-current portion		
An equity investee (note (b))	32,896	—
Other payables, accruals and advance receipts		
Indirect subsidiaries of CK Hutchison (note (c) and (e))	1,884	1,953
An equity investee (note (a) and (d))	73	148
	<u>1,957</u>	<u>2,101</u>
Other non-current liabilities		
An equity investee (note (d))	592	755
An indirect subsidiary of CK Hutchison (note (e))	8,940	8,716
	<u>9,532</u>	<u>9,471</u>

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) As at June 30, 2023, dividends receivable within one year of US\$20,961,000 was included in amount due from a related party. US\$32,896,000 of dividends receivable beyond one year was included in amount due from a related party, non-current portion.
- (c) Amounts due to indirect subsidiaries of CK Hutchison are unsecured, repayable on demand and interest-bearing if not settled within one month.
- (d) Other deferred income represents amounts recognized from granting of commercial, promotion and marketing rights.
- (e) As at June 30, 2023 and December 31, 2022, a branding liability payable of US\$1,538,000 was included in amounts due to related parties under other payables, accruals and advance receipts. As at June 30, 2023 and December 31, 2022, US\$8,940,000 and US\$8,716,000 of the branding liability payable was included in other non-current liabilities.

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

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Sales	35,933	17,705
Purchases	3,199	3,442
Dividends paid	9,068	—

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

	June 30, 2023	December 31, 2022
	(in US\$'000)	
Accounts receivable	11,848	11,139
Accounts payable	1,652	2,922

16. Income Tax (Expense)/Benefit

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Current tax		
HK	6	80
PRC	976	1,008
U.S. and others	52	1,694
Total current tax	1,034	2,782
Deferred income tax expense/(benefit)	1,696	(6,997)
Income tax expense/(benefit)	2,730	(4,215)

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 income/(loss) before income taxes and equity in earnings of equity investees is as follows:

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Income/(loss) before income taxes and equity in earnings of equity investees	137,088	(200,636)
Tax calculated at the statutory tax rate of the Company	22,620	(33,105)
Tax effects of:		
Different tax rates applicable in different jurisdictions	(1,423)	1,771
Tax valuation allowance	(2,898)	41,374
Preferential tax rate difference	(39)	(67)
Preferential tax deduction and credits	(17,735)	(18,169)
Expenses not deductible for tax purposes	2,829	3,070
Utilization of previously unrecognized tax losses	(39)	(1)
Withholding tax on undistributed earnings of PRC entities	1,755	1,681
Income not subject to tax	(2,478)	(611)
Others	138	(158)
Income tax expense/(benefit)	2,730	(4,215)

17. Earnings/(Losses) Per Share

(i) Basic earnings/(losses) per share

Basic earnings/(losses) per share is calculated by dividing the net income/(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 earnings/(losses) per share.

	Six Months Ended June 30,	
	2023	2022
Weighted average number of outstanding ordinary shares in issue	846,928,863	849,283,553
Net income/(loss) attributable to the Company (US\$'000)	168,551	(162,861)
Basic earnings/(losses) per share attributable to the Company (US\$ per share)	0.20	(0.19)

(ii) Diluted earnings/(losses) per share

Diluted earnings/(losses) per share is calculated by dividing net income/(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 options and LTIP awards issued by the Company using the treasury stock method.

	Six Months Ended June 30,	
	2023	2022
Weighted average number of outstanding ordinary shares in issue	846,928,863	849,283,553
Effect of share options and LTIP awards (note)	20,061,747	—
Weighted average number of outstanding ordinary shares in issue and dilutive ordinary share equivalents outstanding	866,990,610	849,283,553
Net income/(loss) attributable to the Company (US\$'000)	168,551	(162,861)
Diluted earnings/(losses) per share attributable to the Company (US\$ per share)	0.19	(0.19)

Note: For the six months ended June 30, 2022, 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.

18. Segment Reporting

The Group's operating segments are as follows:

- (i) Oncology/Immunology: focuses on discovering, developing, and commercializing targeted therapies and immunotherapies for the treatment of cancer and immunological diseases. Oncology/Immunology is further segregated into two core business areas:
 - (a) R&D: comprises research and development activities covering drug discovery, development, manufacturing and regulatory functions as well as administrative activities to support research and development operations; and
 - (b) Marketed Products: comprises the sales, marketing, manufacture and distribution of drugs developed from research and development activities including out-licensed marketed products.
- (ii) Other Ventures: comprises other commercial businesses which include the sales, marketing, manufacture and distribution of other prescription drugs and consumer health products.

The performance of the reportable segments is assessed based on segment net income/(loss) attributable to the Company.

The segment information is as follows:

Six Months Ended June 30, 2023

	Oncology/Immunology							Total
	R&D			Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC	Subtotal	PRC	Unallocated	
	(in US\$'000)							
Revenue from external customers	9,977	269,057	279,034	80,149	359,183	173,691	—	532,874
Interest income	438	1	439	—	439	238	15,198	15,875
Interest expense	—	—	—	—	—	—	(224)	(224)
Equity in earnings of equity investees, net of tax	—	—	—	—	—	35,110	—	35,110
Income tax (expense)/benefit	(86)	(7)	(93)	107	14	(939)	(1,805)	(2,730)
Net (loss)/income attributable to the Company	(83,628)	205,010	121,382	12,971	134,353	37,180	(2,982)	168,551
Depreciation/amortization	(3,263)	(250)	(3,513)	—	(3,513)	(165)	(134)	(3,812)
Additions to non-current assets (other than financial instruments and deferred tax assets)	30,296	110	30,406	—	30,406	243	15	30,664

June 30, 2023

	Oncology/Immunology							Total
	R&D			Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC	Subtotal	PRC	Unallocated	
	(in US\$'000)							
Total assets	152,736	33,995	186,731	64,260	250,991	170,366	876,140	1,297,497
Property, plant and equipment	93,840	1,940	95,780	—	95,780	826	223	96,829
Right-of-use assets	4,887	2,867	7,754	—	7,754	838	600	9,192
Leasehold land	11,387	—	11,387	—	11,387	—	—	11,387
Goodwill	—	—	—	—	—	3,064	—	3,064
Other intangible asset	—	—	—	—	—	52	—	52
Investments in equity investees	—	—	—	—	—	37,740	—	37,740

Six Months Ended June 30, 2022

	Oncology/Immunology							Total
	R&D			Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC	Subtotal	PRC	Unallocated	
	(in US\$'000)							
Revenue from external customers	27,552	—	27,552	63,517	91,069	110,978	—	202,047
Interest income	376	—	376	—	376	92	1,514	1,982
Interest expense	—	—	—	—	—	—	(404)	(404)
Equity in earnings of equity investees, net of tax	(2)	—	(2)	—	(2)	33,551	—	33,549
Income tax (expense)/benefit	(255)	6,912	6,657	(436)	6,221	(317)	(1,689)	4,215
Net (loss)/income attributable to the Company	(92,645)	(96,156)	(188,801)	9,006	(179,795)	35,423	(18,489)	(162,861)
Depreciation/amortization	(3,827)	(237)	(4,064)	—	(4,064)	(154)	(158)	(4,376)
Additions to non-current assets (other than financial instruments and deferred tax assets)	8,947	227	9,174	—	9,174	160	13	9,347

December 31, 2022

	Oncology/Immunology							Total
	R&D			Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC	Subtotal	PRC	Unallocated	
	(in US\$'000)							
Total assets	221,337	30,281	251,618	45,984	297,602	235,500	496,343	1,029,445
Property, plant and equipment	72,775	2,103	74,878	—	74,878	735	334	75,947
Right-of-use assets	3,350	3,167	6,517	—	6,517	1,308	897	8,722
Leasehold land	11,830	—	11,830	—	11,830	—	—	11,830
Goodwill	—	—	—	—	—	3,137	—	3,137
Other intangible asset	—	—	—	—	—	85	—	85
Investments in equity investees	316	—	316	—	316	73,461	—	73,777

Revenue from external customers is after elimination of inter-segment sales. Sales between segments are carried out at mutually agreed terms. The amounts eliminated attributable to sales between PRC and U.S. and others under

Oncology/Immunology segment were US\$17,303,000 and US\$68,015,000 for the six months ended June 30, 2023 and 2022 respectively.

A summary of customers who accounted for over 10% of the Group's revenue for the six months ended June 30, 2023 and 2022 is as follows:

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Customer A	269,057	—
Customer B	(note)	39,034
Customer C	(note)	36,282

Note: Customer did not account for over 10% of the Group's revenue during the six months ended June 30, 2023.

Customer A, B and C are included in Oncology/Immunology.

Unallocated expenses mainly represent corporate expenses which include corporate administrative costs, corporate employee benefit expenses and the relevant share-based compensation expenses, net of interest income. Unallocated assets mainly comprise cash and cash equivalents and short-term investments.

19. Note to Condensed Consolidated Statements of Cash Flows

Reconciliation of net income/(loss) for the period to net cash generated from/(used in) operating activities:

	Six Months Ended June 30,	
	2023	2022
	(in US\$'000)	
Net income/(loss)	169,468	(162,872)
Adjustments to reconcile net income/(loss) to net cash generated from/(used in) operating activities		
Depreciation and amortization	3,812	4,376
Share-based compensation expense—share options	3,239	3,741
Share-based compensation expense—LTIP	10,551	11,637
Equity in earnings of equity investees, net of tax	(35,110)	(33,549)
Dividend received from SHPL	14,615	22,692
Changes in right-of-use assets	(720)	2,221
Fair value losses on warrant	—	2,452
Other adjustments	(78)	1,665
Changes in working capital		
Accounts receivable	(31,348)	6,397
Other receivables, prepayments and deposits	(2,296)	10,585
Amount due from a related party	—	150
Inventories	2,815	(10,362)
Accounts payable	(16,540)	9,828
Other payables, accruals and advance receipts	(34,188)	39,235
Deferred revenue	142,003	3,120
Others	180	(1,175)
Total changes in working capital	60,626	57,778
Net cash generated from/(used in) operating activities	226,403	(89,859)

20. 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 financial position, results of operations 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, results of operations or cash flows for the periods in which the unfavorable outcome occurs, and potentially in future periods.

On May 17, 2019, Luye Pharma Hong Kong Ltd. ("Luye") 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 Luye have no basis for termination. As a result, the Group commenced legal proceedings in 2019 in order to seek damages. On October 21, 2021 (and a decision on costs and interest in December 2021), the Group was awarded an amount of RMB253.2 million (equivalent to US\$35.4 million) with interest of 5.5% per annum from the date of the award until payment and recovery of costs of approximately US\$2.2 million (collectively the "Award"). On June 27, 2022, Luye provided the Group a bank guarantee of up to RMB286.0 million to cover the Award amounts, pending the outcome of an application by Luye to the High Court of Hong Kong to set aside the Award. On July 26, 2022, Luye's application to set aside the Award was dismissed by the High Court with costs awarded in favor of the Group. On October 7, 2022, Luye filed a Notice of Appeal to the Court of Appeal regarding the dismissal and the notice was accepted on November 8, 2022. On June 6, 2023, a Court of Appeal hearing was held and a judgement is expected but yet to be received. The legal proceedings are ongoing and as no Award amounts have been received as at the issuance date of these condensed consolidated financial statements, no Award amounts have been recognized and no adjustment has been made to Seroquel-related balances as at June 30, 2023. Such Seroquel-related balances include accounts receivable, long-term prepayment, accounts payable and other payables of US\$1.1 million, US\$0.3 million, US\$0.9 million and US\$1.1 million respectively.

21. Subsequent Events

The Group evaluated subsequent events through July 31, 2023, which is the date when the interim unaudited condensed consolidated financial statements were issued.

22. Reconciliation between U.S. GAAP and International Financial Reporting Standards

These interim unaudited condensed consolidated financial statements are prepared in accordance with U.S. GAAP, which differ in certain respects from International Financial Reporting Standards (“IFRS”). The effects of material differences prepared under U.S. GAAP and IFRS are as follows:

(i) Reconciliation of condensed consolidated statements of operations

	Six Months Ended June 30, 2023		
	Amounts as reported under U.S. GAAP	IFRS adjustment Lease amortization (note (a)) (in US\$'000)	Amounts under IFRS
Costs of goods—third parties	(182,380)	34	(182,346)
Research and development expenses	(144,633)	18	(144,615)
Selling expenses	(26,423)	23	(26,400)
Administrative expenses	(41,840)	80	(41,760)
Total operating expenses	(421,220)	155	(421,065)
Other income/(expense), net	25,434	(163)	25,271
Income/(loss) before income taxes and equity in earnings of equity investees	137,088	(8)	137,080
Equity in earnings of equity investees, net of tax	35,110	(2)	35,108
Net income/(loss)	169,468	(10)	169,458
Less: Net (income)/loss attributable to non-controlling interests	(917)	(8)	(925)
Net income/(loss) attributable to the Company	168,551	(18)	168,533

	Six Months Ended June 30, 2022		
	Amounts as reported under U.S. GAAP	IFRS adjustment Lease amortization (note (a)) (in US\$'000)	Amounts under IFRS
	Costs of goods—third parties	(115,567)	22
Research and development expenses	(181,741)	14	(181,727)
Selling expenses	(22,221)	25	(22,196)
Administrative expenses	(57,521)	93	(57,428)
Total operating expenses	(398,801)	154	(398,647)
Other income/(expense), net	(3,882)	(161)	(4,043)
Income/(loss) before income taxes and equity in earnings of equity investees	(200,636)	(7)	(200,643)
Equity in earnings of equity investees, net of tax	33,549	(9)	33,540
Net income/(loss)	(162,872)	(16)	(162,888)
Less: Net (income)/loss attributable to non-controlling interests	11	(1)	10
Net income/(loss) attributable to the Company	(162,861)	(17)	(162,878)

(ii) Reconciliation of condensed consolidated balance sheets

	June 30, 2023					Amounts under IFRS
	Amounts as reported under U.S. GAAP	IFRS adjustments			LTIP classification (note (d))	
		Lease amortization (note (a))	Issuance costs (note (b))	Capitalization of rights (note (c))		
						(in US\$'000)
Investments in equity investees	37,740	(38)	—	—	—	37,702
Other non-current assets	39,547	(236)	—	15,093	—	54,404
Total assets	1,297,497	(274)	—	15,093	—	1,312,316
Other payables, accruals and advance receipts	227,212	—	—	—	(441)	226,771
Total current liabilities	340,863	—	—	—	(441)	340,422
Total liabilities	497,480	—	—	—	(441)	497,039
Additional paid-in capital	1,506,280	—	(697)	—	441	1,506,024
Accumulated losses	(803,057)	(263)	697	16,084	—	(786,539)
Accumulated other comprehensive loss	(7,800)	13	—	(1,016)	—	(8,803)
Total Company's shareholders' equity	782,039	(250)	—	15,068	441	797,298
Non-controlling interests	17,978	(24)	—	25	—	17,979
Total shareholders' equity	800,017	(274)	—	15,093	441	815,277

	December 31, 2022					Amounts under IFRS
	Amounts as reported under U.S. GAAP	IFRS adjustments			LTIP classification (note (d))	
		Lease amortization (note (a))	Issuance costs (note (b))	Capitalization of rights (note (c))		
(in US\$'000)						
Investments in equity investees	73,777	(37)	—	—	—	73,740
Other non-current assets	39,833	(233)	—	15,370	—	54,970
Total assets	1,029,445	(270)	—	15,370	—	1,044,545
Other payables, accruals and advance receipts	264,621	—	—	—	(3,701)	260,920
Total current liabilities	353,903	—	—	—	(3,701)	350,202
Total liabilities	392,575	—	—	—	(3,701)	388,874
Additional paid-in capital	1,497,273	—	(697)	—	3,701	1,500,277
Accumulated losses	(971,481)	(246)	697	16,084	—	(954,946)
Accumulated other comprehensive loss	(1,903)	8	—	(739)	—	(2,634)
Total Company's shareholders' equity	610,367	(238)	—	15,345	3,701	629,175
Non-controlling interests	26,503	(32)	—	25	—	26,496
Total shareholders' equity	636,870	(270)	—	15,370	3,701	655,671

Notes:

(a) Lease amortization

Under U.S. GAAP, for operating leases, the amortization of right-of-use assets and the interest expense element of lease liabilities are recorded together as lease expenses, which results in a straight-line recognition effect in the condensed consolidated statements of operations.

Under IFRS, all leases are accounted for like finance leases where right-of-use assets are generally depreciated on a straight-line basis while lease liabilities are measured under the effective interest method, which results in higher expenses at the beginning of the lease term and lower expenses near the end of the lease term.

(b) Issuance costs

Under U.S. GAAP and IFRS, there are differences in the criteria for capitalization of issuance costs incurred in the offering of equity securities.

(c) Capitalization of development and commercial rights

Under U.S. GAAP, the acquired development and commercial rights do not meet the capitalization criteria as further development is needed as of the acquisition date and there is no alternative future use. Such rights are considered as in-process research and development and were expensed to research and development expense.

Under IFRS, the acquired development and commercial rights were capitalized to intangible assets. The recognition criterion is always assumed to be met as the price already reflects the probability that future economic benefits will flow to the Group.

(d) LTIP classification

Under U.S. GAAP, LTIP awards with performance conditions are classified as liability-settled awards prior to the determination date as they settle in a variable number of shares based on a determinable monetary amount, which is determined upon the actual achievement of performance targets. After the determination date, the LTIP awards are reclassified as equity-settled awards.

Under IFRS, LTIP awards are classified as equity-settled awards, both prior to and after the determination date, as they are ultimately settled in ordinary shares or the equivalent ADS of the Company instead of cash.

23. Dividends

No dividend has been declared or paid by the Company for the six months ended June 30, 2023 and 2022.

As at the date of this announcement, the Directors of the Company are:

Executive Directors:

Mr TO Chi Keung, Simon

(Chairman)

Dr Weiguo SU

*(Chief Executive Officer and
Chief Scientific Officer)*

Mr CHENG Chig Fung, Johnny

(Chief Financial Officer)

Non-executive Directors:

Dr Dan ELDAR

Ms Edith SHIH

Ms Ling YANG

Independent Non-executive Directors:

Mr Paul Rutherford CARTER

(Senior Independent Director)

Mr Graeme Allan JACK

Professor MOK Shu Kam, Tony