

# HUTCHMED Reports 2022 Full Year Results and Provides Business Updates

Landmark licensing deal with Takeda for fruquintinib outside of China, bringing HUTCHMED up to US\$1.13 billion, plus royalties, and demonstrating execution of the new global strategy

Record Full Year 2022 oncology/immunology revenues driven by significant increase in China in-market sales of ELUNATE<sup>®</sup>, SULANDA<sup>®</sup> and ORPATHYS<sup>®</sup> alongside clinical and strategic progress

Company to Host Annual Results Call & Webcast Today at 9 p.m. HKT / 1 p.m. GMT / 8 a.m. EST

Hong Kong, Shanghai & Florham Park, NJ — Tuesday, February 28, 2023: HUTCHMED (China) Limited ("<u>HUTCHMED</u>", the "Company" or "we") (Nasdaq/AIM:HCM; HKEX:13), the innovative, commercial-stage biopharmaceutical company, today reports its financial results for the year ended December 31, 2022 and provides updates on key clinical and commercial developments.

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

# **KEY HIGHLIGHTS**

#### Strategic

- Announced a strategy update, including a prioritization of late-stage assets and a new global partnership approach to bring innovative medicines to patients outside of China
- Signed a landmark licensing agreement with Takeda<sup>1</sup> to license fruquintinib outside of China for a potential total of up to \$1.13 billion, plus royalties on net sales, demonstrating this strategy in action
- Focus on driving near-term value creation and establishing a profitable, sustainable business over the long term

#### Product and pipeline

- FRESCO-2 Phase III data for fruquintinib in refractory metastatic CRC<sup>2</sup>, our first global multi-regional clinical trial and presented at ESMO<sup>3</sup>, met the primary end point of overall survival with a 34% reduction in risk of death
- Started rolling submission of NDA<sup>4</sup> to U.S. FDA<sup>5</sup> for fruquintinib for the treatment of refractory CRC
- Statistically significant PFS<sup>6</sup> benefit in fruquintinib FRUTIGA Phase III in China with supplemental NDA in preparation
- Global SAVANNAH Phase II data for savolitinib showed 52% response rate and 9.6 months duration of response in high MET<sup>7</sup> 2L+ NSCLC<sup>8</sup> patients with no prior chemotherapy
- ORPATHYS<sup>®</sup> (savolitinib) to be included in NRDL<sup>9</sup> effective March 1, 2023
- Over 15 registration/registration-intent studies ongoing with six products

#### Financial

- Oncology/Immunology revenues up 37% (41% CER<sup>10</sup>) to \$163.8 million and in line with guidance
- ELUNATE<sup>®</sup>, SULANDA<sup>®</sup> and ORPATHYS<sup>®</sup> combined in-market sales<sup>11</sup> up 70%
- Substantial cash balance, plus \$400 million upfront payment from Takeda at closing, will position HUTCHMED well on the path to a sustainable business



# 2022 FULL YEAR RESULTS & BUSINESS UPDATES

"I am proud of the progress that we at HUTCHMED have made during 2022," said Mr Simon To, Chairman of HUTCHMED. "This work is already bearing fruit, as indicated not only by the increase in revenues, but also the positive clinical and regulatory progress we have made with fruquintinib – culminating in the successful, post-period licensing agreement with Takeda, marking a significant delivery against the Company's strategy. This out-licensing ensures we remain true to the overall goal of our business of safeguarding access to our innovative medicines to patients globally. Further, our partnerships provide significant financial momentum while we focus on revenue growth from increased product sales in China."

"This strategy of revenue growth and strategic partnerships places us well on the path to a sustainable business. It is this path which will allow us to continue our expansion, as demonstrated by HUTCHMED's continued delivery in China where our oncology commercial team has reached about 900 people to support greater access to our medicines; our ongoing development of savolitinib, which became our third product on the NRDL; and the continued ability of our business to develop medicines towards global markets. It is through this ability that we expect to see multiple New Drug Applications being made not only in China but with key regulators around the world as we look to extend our ability to bring potentially life changing medicines to patients around the world."

"2022 has been a key turning point for HUTCHMED, but I believe it will enable us to truly reach our goal of becoming a global biopharmaceutical company."

**Dr Weiguo Su, Chief Executive Officer and Chief Scientific Officer of HUTCHMED, said,** "2022 was a pivotal year for HUTCHMED. Challenged by difficult market conditions, the team worked incredibly hard to position HUTCHMED for success today as well as for a promising future. In November, we announced a new strategy that focuses on accelerating our path to a sustainable and profitable business, which involves a reprioritization of pipeline assets and a partnership approach for bringing our innovative medicines more efficiently to patients outside of China. We believe that this new strategy has unlocked greater value in the Company and we are already seeing a positive impact from this approach."

"In early 2023 we announced a significant licensing deal with Takeda for the global development, commercialization and manufacturing of fruquintinib, outside of China. We are pleased to have attracted such a strong partner and to place fruquintinib in the hands of a company with the scale, expertise, resources and commitment to maximize its success globally, as we believe we are already doing in China. The expected proceeds from the deal notably extends our cash runway, and the additional bandwidth allows us to continue to pursue value-driving opportunities from our internal pipeline while supporting our commercial growth in China. The Takeda deal perfectly exemplifies our global partnership approach and showcases our commitment to fulfilling our promises, swiftly and effectively."

"This approach goes hand in hand with the strategic prioritization of our pipeline. This includes focusing our development efforts on late-stage assets through clinical development and towards patients. Ultimately, this is how we will accelerate our path to a sustainable business over the long term. As part of our pipeline prioritization, we have reduced some funding to select international clinical programs and we look to further develop of some of these programs through partnerships. Specifically, these changes affect amdizalisib, HMPL-306 and HMPL-760 international clinical programs. We will continue the surufatinib clinical program in Japan where a bridging study is fully recruited. Going forward, HUTCHMED still intends to continue to run early phase development programs for select drug candidates in the U.S., EU and Japan including sovleplenib where we believe our compounds are differentiated from a global perspective. This does not impact our commitment to patients, which, if anything, has intensified as we sharpen our focus on a smaller set of programs that we believe have the most immediate patient impact.

I am proud of what the team has achieved this year amidst very difficult times for the sector, and feel very positive about our outlook."



# I. COMMERCIAL OPERATIONS

- Total revenues increased 20% (24% CER) to \$426.4 million in 2022 (2021: \$356.1m), driven by commercial progress on our three in-house developed oncology drugs in China;
- Oncology/Immunology consolidated revenues up 37% (41% CER) to \$163.8 million (2021: \$119.6m);
- ELUNATE<sup>®</sup> (fruquintinib) in-market sales in 2022 increased 32% to \$93.5 million (2021: \$71.0m), reflecting its expanding lead in market share, particularly in tier 2 and 3 cities;
- SULANDA<sup>®</sup> (surufatinib) in-market sales in 2022 increased 178% to \$32.3 million (2021: \$11.6m), reflecting its first time NRDL inclusion which started in January 2022;
- **ORPATHYS**<sup>®</sup> (savolitinib) in-market sales in 2022 increased 159% to \$41.2 million (2021: \$15.9m) following its launch in the second half of 2021 through AstraZeneca's<sup>12</sup> extensive oncology commercial organization. Rapid initial self-pay uptake due to being the first-in-class selective MET inhibitor in China, expect continued uptake to be supported by NRDL inclusion starting March 1, 2023;
- TAZVERIK® (tazemetostat) successfully launched in Hainan province in China in June 2022; and
- Successful management of commercial operations to expand coverage of oncology hospitals and physicians despite challenges of pandemic-related lockdowns in the first half of 2022.

\$'millions	In-ma	arket Sale	S*	Consolidated Revenues**		
	2022	2021	% Change	2022	2021	% Change
ELUNATE <sup>®</sup>	\$93.5	\$71.0	+32%	\$69.9	\$53.5	+31%
SULANDA®	\$32.3	\$11.6	+178%	\$32.3	\$11.6	+178%
ORPATHYS <sup>®</sup>	\$41.2	\$15.9	+159%	\$22.3	\$11.3	+97%
TAZVERIK®	\$0.1	_	_	\$0.1	_	_
Product Sales	\$167.1	\$98.5	+70%	\$124.6	\$76.4	+63%
Other R&D <sup>13</sup> services income				\$24.2	\$18.2	+33%
Milestone payment				\$15.0	\$25.0	-40%
Total Oncology/Immunology				\$163.8	\$119.6	+37%

\* = For ELUNATE<sup>®</sup> and ORPATHYS<sup>®</sup>, represents total sales to third parties as provided by Lilly<sup>14</sup> and AstraZeneca, respectively; and ELUNATE<sup>®</sup> sales to other third parties as invoiced by HUTCHMED.

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

# II. REGULATORY UPDATES

#### China

- Received Breakthrough Therapy Designation in China for sovleplenib (HMPL-523) in January 2022 for the treatment of ITP<sup>15</sup>;
- Received approval for TAZVERIK<sup>®</sup> in the Hainan Boao Lecheng International Medical Tourism Pilot Zone in May 2022 for the treatment of certain patients with epithelioid sarcoma or follicular lymphoma; and
- **Received Macau approvals for ELUNATE® and SULANDA®**, the first drugs approved in the territory based on China NMPA<sup>16</sup> approval, following regulatory updates in Macau.

#### Ex-China

• Fruquintinib rolling NDA submission to U.S. FDA initiated in December 2022 for the treatment of refractory CRC. The U.S. FDA granted Fast Track Designation for the development of fruquintinib for the treatment of patients with metastatic CRC in June 2020, enabling the company to submit sections of the NDA on a rolling basis;



- Fruquintinib submissions to the EMA<sup>17</sup> and the Japanese PMDA<sup>18</sup> to follow the completion of the US NDA submission; all expected to be completed in 2023;
- Savolitinib granted Fast Track Designation by the FDA for the combination treatment with TAGRISSO<sup>®</sup> of NSCLC patients harboring MET overexpression and/or amplification following progression on TAGRISSO<sup>®</sup>; and
- Surufatinib U.S. NDA and EMA MAA<sup>19</sup> withdrawn:
  - A Complete Response Letter regarding the US NDA (CRL) was issued in April 2022 by the U.S. FDA, citing the requirement of a multi-regional clinical trial in a more representative patient population. Following the Letter, the U.S. NDA was withdrawn in January 2023; the MAA was withdrawn in August 2022, following interactions with EMA reviewers which suggested that there is a low probability of a positive opinion;
  - In Japan, the bridging study is continuing and a pre-NDA PMDA consultation is targeted for the first half of 2023; and
  - <sup>o</sup> Pandemic-related issues concerning inspection access contributed to FDA and EMA actions.

# **III. CLINICAL DEVELOPMENT ACTIVITIES in 2022**

# *Savolitinib (ORPATHYS<sup>®</sup> 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

- Presentation of SAVANNAH global Phase II study data showing improved response rates with increasing levels of MET aberration for the TAGRISSO<sup>®</sup> combination (NCT03778229) in NSCLC patients harboring EGFR<sup>20</sup> mutation and MET amplification or overexpression at WCLC<sup>21</sup> 2022. Overall results demonstrated strong ORR<sup>22</sup>, DoR<sup>23</sup> and PFS among patients with higher MET levels, particularly among those with no prior chemotherapy;
- Aligned with FDA for the pivotal Phase II study for accelerated approval of the TAGRISSO<sup>®</sup> combination for NSCLC MET patients following progression on TAGRISSO<sup>®</sup>, and began enrolling;
- Initiated SAFFRON, a global, pivotal Phase III study of the TAGRISSO<sup>®</sup> combination (NCT05261399), which triggered a \$15 million milestone payment. Enrolled patients will have MET levels consistent with the higher MET level patient groups in SAVANNAH and have had no prior chemotherapy;
- Enrolling SACHI, a pivotal Phase III study of the TAGRISSO<sup>®</sup> combination in China for NSCLC patients with MET amplification following progression on EGFR inhibitor treatment (NCT05015608);
- Enrolling SANOVO, a pivotal Phase III study of the TAGRISSO<sup>®</sup> combination in China in NSCLC patients harboring EGFR mutation and MET overexpression, comparing the combination with TAGRISSO<sup>®</sup> monotherapy (NCT05009836);
- Presented final Phase II OS<sup>24</sup> in patients with MET exon 14 skipping alteration NSCLC at ELCC<sup>25</sup> 2022 (NCT02897479);
- Enrolling the confirmatory China Phase IIIb study in MET exon 14 skipping altered NSCLC in both first-line and second-line and above patients (NCT04923945);
- Enrolling SAMETA, a global Phase III study in MET-driven PRCC<sup>26</sup> of the IMFINZI<sup>®</sup> combination comparing to sunitinib (NCT05043090);
- Enrolled a China Phase II study in gastric cancer patients who have failed at least one line of systemic treatment (NCT04923932); and
- Initiated SOUND, a China Phase II study of the IMFINZI<sup>®</sup> combination in EGFR wild-type NSCLC patients with MET alterations (NCT05374603).

Potential upcoming clinical and regulatory milestones for savolitinib:

- **Convert the gastric cancer Phase II study to a registration trial**, following discussion with NMPA in the first half of 2023; and
- Complete enrollment of SAVANNAH pivotal Phase II study.



**Fruquintinib** (**ELUNATE**<sup>®</sup> **in China**), a highly selective oral inhibitor of VEGFR<sup>27</sup> 1/2/3 designed to improve kinase selectivity to minimize off-target toxicity and thereby improve tolerability; approved and launched in China

- Presented positive results of the global Phase III FRESCO-2 registration trial (NCT04322539) in 691 refractory metastatic CRC patients, recruited from 14 countries including U.S., EU, Japan and Australia at ESMO in September 2022. Treatment with fruquintinib resulted in a statistically significant and clinically meaningful increase in the primary endpoint of OS and the key secondary endpoint of PFS compared to placebo;
- Presented preliminary data from the U.S. Phase Ib monotherapy study of fruquintinib in patients with refractory metastatic CRC (NCT03251378) at 2022 ASCO GI<sup>28</sup>; and
- **Reported top-line results of the FRUTIGA China Phase III registration study** (NCT03223376) in 703 advanced gastric cancer patients. The study met one of the primary endpoints of statistically significant improvement in PFS, which is clinically meaningful. The other primary endpoint of OS was not statistically significant. There were statistically significant improvements in secondary endpoints including ORR and DCR<sup>29</sup>, and improved DoR; and
- Initiated China Phase III study of combination with PD-1 <sup>30</sup> inhibitor sintilimab in RCC <sup>31</sup> (NCT05522231).

Potential upcoming clinical and regulatory milestones for fruquintinib:

- Submit a supplementary NDA to the NMPA for fruquintinib in combination with paclitaxel in the treatment of advanced gastric cancer in H1 2023, supported by results of the FRUTIGA study;
- **Complete recruitment of a Phase II registration enabling study for endometrial cancer** of fruquintinib in combination with PD-1 inhibitor sintilimab around mid-2023 (NCT03903705);
- Submit FRUTIGA results for presentation at a scientific conference;
- Submit for presentation further Phase II data of fruquintinib with PD-1 inhibitors; and
- **Publication of FRESCO-2** results in a peer-reviewed scientific journal.

*Surufatinib (SULANDA<sup>®</sup> in China)*, an oral inhibitor of VEGFR, FGFR<sup>32</sup> and CSF-1R<sup>33</sup> designed to inhibit tumor angiogenesis and promote the body's immune response against tumor cells via tumor associated macrophage regulation; approved and launched in China

- **Presented a pooled analysis of safety data from the SANET-p and SANET-ep studies** at the 2022 ASCO<sup>34</sup> annual meetings; and
- Presented data from the Phase Ib/II global tislelizumab combination study at NANETS<sup>35</sup> 2022.

Potential upcoming clinical and regulatory milestones for surufatinib:

• **Complete bridging study in NET patients in Japan** (NCT05077384) in the first half of 2023 and discuss results with the Japanese PMDA.

**Sovleplenib (HMPL-523)**, an investigative and highly selective oral inhibitor of Syk<sup>36</sup>, an important component of the Fc receptor and B-cell receptor signaling pathway

• Fully enrolled ESLIM-01 China Phase III study in primary ITP (NCT03951623) in December 2022.

Potential upcoming clinical milestones for sovleplenib:

- Report top-line results from ESLIM-01 China Phase III in the second half of 2023; and
- Complete Phase II Proof-of-Concept study in warm AIHA<sup>37</sup> in China and decide on whether to proceed into Phase III.

**Amdizalisib** (HMPL-689), an investigative and highly selective oral inhibitor of PI3Kδ<sup>38</sup> designed to address the gastrointestinal and hepatotoxicity associated with currently approved and clinical-stage PI3Kδ 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 China combination trial with tazemetostat 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 H2 2023.

**Tazemetostat (TAZVERIK<sup>®</sup> in the U.S., Japan and the Hainan Pilot Zone)**, a first-in-class, oral inhibitor of EZH2 licensed from Ipsen<sup>39</sup> subsidiary Epizyme<sup>40</sup> in China

- **Initiated a China bridging study in follicular lymphoma** in July 2022 for conditional registration based on U.S. approvals (NCT05467943);
- Ipsen presented updated data from the Phase Ib portion of the global SYMPHONY-1 Phase III trial at ASH (NCT04224493) of tazemetostat combined with lenalidomide and rituximab (R<sup>2</sup>) in patients with relapsed or refractory follicular lymphoma after at least one prior line of therapy; and
- Initiated the China portion of the global SYMPHONY-1 Phase III trial in September 2022.

#### Earlier stage investigational drug candidates

In addition to the six 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 IDH1/2<sup>41</sup> designed to address resistance to currently marketed IDH inhibitors; **HMPL-760**, a highly selective, third-generation oral inhibitor of BTK<sup>42</sup> with improved potency versus first generation BTK inhibitors against both wild type & C481S mutant enzymes; **HMPL-453**, a highly selective oral inhibitor of FGFR 1/2/3; **HMPL-295**, a highly selective oral inhibitor of ERK<sup>43</sup> in the MAPK pathway <sup>44</sup> 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; and **HMPL-A83**, a differentiated, red blood cell sparing CD47 monoclonal antibody.

Subject to data and consultation with the CDE<sup>45</sup>, several of these earlier stage drug candidates have potential to move into registration trials in 2023 and early 2024. We have recently agreed a registration enabling trial design for HMPL-453 for the treatment of IHCC<sup>46</sup> with the CDE and preparations are underway to start the study. Results supporting this decision will be submitted for scientific presentation in 2023.

# **IV. COLLABORATION UPDATES**

#### Takeda Exclusive Worldwide License for Fruquintinib Outside China

Subject to customary closing conditions, including completion of antitrust regulatory reviews:

- Takeda will become responsible for development, manufacturing and commercialization in all indications and territories outside of mainland China, Hong Kong and Macau; and
- HUTCHMED will be eligible to receive up to \$1.13 billion, including \$400 million upfront 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.

#### Inmagene candidates discovered by HUTCHMED

**Two Phase I trials initiated** in Australia and the U.S. on two HUTCHMED drug candidates being developed by Inmagene: **IMG-007**, an investigative OX40 antagonistic monoclonal antibody designed to selectively shut down OX40+ T cell function; and **IMG-004**, a reversible, non-covalent, highly selective oral BTK inhibitor designed to target immunological diseases.

# V. OTHER VENTURES

Other Ventures include our profitable prescription drug marketing and distribution platforms

- Other Ventures consolidated revenues increased by 11% (15% at CER) to \$262.6 million (2021: \$236.5m);
- SHPL<sup>47</sup> non-consolidated joint venture revenues increased by 11% (14% at CER) to \$370.6 million (2021: \$332.6m);



- Consolidated net income attributable to HUTCHMED from our Other Ventures increased by 16% (17% at CER) to \$54.6 million (2021: \$47.3m which excluded \$95.6m related to HBYS<sup>48</sup>), which was primarily due to the net income contributed from SHPL of \$49.9 million (2021: \$44.7m); and
- We continue to review divestment and equity capital market options and we have started the process for a share reform of the SHPL joint venture.

# VI. IMPACT OF COVID-19

COVID-19 had some impact on our research, clinical studies and our commercial activities in 2022, particularly with respect to hospital lockdowns, travel restrictions, and shipping difficulties. Clinical sites in Shanghai were particularly impacted during April and May 2022. Measures were put in place to reduce the impact of such restrictions to the extent possible, including online patient follow-up and the retention of core research teams on-site to maintain critical activities, with business returning to normal in June. Restrictive measures related to the COVID-19 pandemic have gradually been lifted in China starting from December 2022, and we expect the travel, social and economic activities to normalize.

# VII. SUSTAINABILITY

HUTCHMED has made continued progress in its commitment to the long-term sustainability of its businesses and communities in which it conducts business, including:

- Enhanced disclosures, including publishing our second <u>Sustainability Report</u>, and publishing eight new <u>governance and sustainability-related policies and statements</u>;
- **Strengthened governance**, including establishing a four-tier governance framework to facilitate oversight and implementation of sustainability issues;
- **Committed to 11 short- to long-term sustainability goals and targets**, incorporated sustainability KPIs on goals and targets into management's performance-based remuneration;
- **Comprehensive stakeholder engagement conducted** with over 2,400 key internal and external stakeholders involving quantitative and qualitative assessments, and a materiality analysis to help identify the most material sustainability issues to the Company;
- Enhanced sustainability awareness building in over 20 meetings/sessions during the year amongst the general staff, the Sustainability Working Group, senior management, the Sustainability Committee and the Board; and
- **Climate risks action**, including an assessment to identify climate-related risks and opportunities for the Company, and following the recommended disclosure framework of the Task Force on Climate-related Financial Disclosures (TCFD).

We believe all these efforts will guide us towards a more sustainable future. The 2022 Sustainability Report will be published alongside our 2022 Annual Report in due course and will include further information on HUTCHMED sustainability initiatives and their performance.

#### VIII. U.S. ACCOUNTING OVERSIGHT

As had been expected, in 2022 the U.S. Securities and Exchange Commission (SEC) named over 170 Chinabased companies, including HUTCHMED, to its conclusive list of public companies identified as having retained a registered public accounting firm that the Public Company Accounting Oversight Board ("PCAOB") is unable to inspect to investigate completely. However, on December 15, 2022, the PCAOB announced that it was able to inspect and investigate completely registered public accounting firms headquartered in mainland China and Hong Kong and vacated its prior determination that it was unable to inspect or investigate them completely. As a result, we do not expect to be identified as a Commission-Identified Issuer for the fiscal year ended December 31, 2022 after we file our annual report on Form 20-F for such fiscal year.

This has had no impact on the business operations of the Company.



# FULL YEAR 2022 FINANCIAL RESULTS

Cash, Cash Equivalents and Short-Term Investments were \$631.0 million as of December 31, 2022 compared to \$1,011.7 million as of December 31, 2021.

- Adjusted Group (non-GAAP<sup>49</sup>) net cash flows excluding financing activities in 2022 were -\$297.9 million (2021: -\$73.5m) mainly due to increased spending on Oncology/Immunology R&D; and
- Net cash used in financing activities in 2022 totaled \$82.8 million (2021: net cash generated from financing activities of \$650.0m primarily from the offering of shares on HKEX<sup>50</sup>) mainly due to the repayments of bank borrowings, dividends paid to non-controlling shareholders of subsidiaries and purchases of ADSs<sup>51</sup> by a trustee for the settlement of equity awards.

#### Revenues for the year ended December 31, 2022 were \$426.4 million compared to \$356.1 million in 2021.

 Oncology/Immunology consolidated revenues increased 37% (41% at CER) to \$163.8 million (2021: \$119.6m) resulting from:

**ELUNATE**<sup>®</sup> **revenues increased 31% to \$69.9 million** (2021: \$53.5m) in manufacturing revenues, promotion and marketing service revenues and royalties, as our in-house sales team increased in-market sales 32% to \$93.5 million (2021: \$71.0m), as provided by Lilly;

**SULANDA® revenues increased 178% to \$32.3 million** (2021: \$11.6m), after inclusion on the NRDL starting in January 2022;

**ORPATHYS<sup>®</sup> revenues increased 97% to \$22.3 million** (2021: \$11.3m), in manufacturing revenues and royalties following its launch in the second half of 2021. AstraZeneca reported \$41.2 million inmarket sales (2021: \$15.9m) of ORPATHYS<sup>®</sup> in 2022;

**TAZVERIK® revenues of \$0.1 million following its successful launch in Hainan province** in June 2022;

**Milestone payment of \$15.0 million** (2021: \$25.0m milestone payment upon first sale of ORPATHYS<sup>®</sup> in China), to us by AstraZeneca, related to the initiation of SAFFRON; and

**Other R&D services income of \$24.2 million** (2021: \$18.2m), which were primarily fees from AstraZeneca and Lilly for the management of development activities in China.

• Other Ventures consolidated revenues increased 11% (15% at CER) to \$262.6 million (2021: \$236.5m), mainly due to higher sales of prescription drugs. This excludes the strong 11% (14% at CER) growth in non-consolidated revenues at SHPL of \$370.6 million (2021: \$332.6m).

# *Net Expenses for the year ended December 31, 2022 were \$787.2 million compared to \$550.7 million in 2021.*

- **Costs of Revenues** were \$311.1 million (2021: \$258.2m), the majority of which were the cost of thirdparty prescription drug products marketed through our profitable Other Ventures, as well as costs associated with ELUNATE<sup>®</sup>, including the provision of promotion and marketing services to Lilly, and the costs for SULANDA<sup>®</sup> and ORPATHYS<sup>®</sup> which commenced commercial sales in July 2021;
- **R&D Expenses** were \$386.9 million (2021: \$299.1m), which increased mainly as a result of an expansion in the active development of our novel oncology drug candidates. Our international clinical and regulatory operations in the U.S. and Europe incurred expenses of \$170.9 million (2021: \$140.1m), while R&D expenses in China were \$216.0 million (2021: \$159.0m);
- **SG&A Expenses**<sup>52</sup> were \$136.1 million (2021: \$127.1m), which increased primarily due to higher staff costs and selling expenses to support the expansion of our Oncology/Immunology commercial operations; and
- **Other Items** generated net income of \$46.9 million (2021: \$133.7m), which decreased primarily due to a one-off gain of \$82.9 million in 2021 related to the divestment of HBYS.

# *Net Loss attributable to HUTCHMED for the year ended December 31, 2022 was \$360.8 million compared to \$194.6 million in 2021.*

• The net loss attributable to HUTCHMED in 2022 was \$0.43 per ordinary share / \$2.13 per ADS, compared to net loss attributable to HUTCHMED of \$0.25 per ordinary share / \$1.23 per ADS in 2021.



# **FINANCIAL SUMMARY**

# **Condensed Consolidated Balance Sheets Data** (in \$'000)

(in \$ 000)	As of Decem	ber 31,
—	2022	2021
Assets		
Cash and cash equivalents and short-term investments	630,996	1,011,700
Accounts receivable	97,988	83,580
Other current assets	110,904	116,796
Property, plant and equipment	75,947	41,275
Investments in equity investees	73,777	76,479
Other non-current assets	39,833	42,831
Total assets	1,029,445	1,372,661
Liabilities and shareholders' equity		
Accounts payable	71,115	41,177
Other payables, accruals and advance receipts	264,621	210,839
Bank borrowings	18,104	26,905
Other liabilities	38,735	54,226
Total liabilities	392,575	333,147
Company's shareholders' equity	610,367	986,893
Non-controlling interests	26,503	52,621
Total liabilities and shareholders' equity	1,029,445	1,372,661



# **Condensed Consolidated Statements of Operations Data** (in \$'000, except share and per share data)

(in \$ 000, except share and per share data)	Year Ended December 31,	
	2022	2021
Revenues:		
Oncology/Immunology – Marketed Products	124,642	76,429
Oncology/Immunology – R&D	39,202	43,181
Oncology/Immunology consolidated revenues	163,844	119,610
Other Ventures	262,565	236,518
Total revenues	426,409	356,128
Operating expenses:		
Costs of revenues	(311,103)	(258,234)
Research and development expenses	(386,893)	(299,086)
Selling and general administrative expenses	(136,106)	(127,125)
Total operating expenses	(834,102)	(684,445)
	(407,693)	(328,317)
Gain on divestment of an equity investee	(407,000)	121,310
Other expense, net	(2,729)	(8,733)
Loss before income taxes and equity in earnings of equity investees	(410,422)	
Income tax benefit/(expense)	283	<b>(215,740)</b> (11,918)
Equity in earnings of equity investees, net of tax	49,753	60,617
Net loss	(360,386)	(167,041)
Less: Net income attributable to non-controlling interests	(449)	(27,607)
Net loss attributable to HUTCHMED	(360,835)	(194,648)
Losses per share attributable to HUTCHMED – basic and diluted	(0.42)	(0.25)
(US\$ per share)	(0.43)	(0.25)
Number of shares used in per share calculation – basic and diluted	847,143,540	792,684,524
Losses per ADS attributable to HUTCHMED – basic and diluted (US\$ per ADS)	(2.13)	(1.23)
Number of ADSs used in per share calculation – basic and diluted	169,428,708	158,536,905
Number of ADOS used in per share calculation – basic and diluted	109,420,700	100,000,900



# FINANCIAL GUIDANCE

We provide financial guidance for 2023 below reflecting expected revenue growth of ELUNATE<sup>®</sup>, SULANDA<sup>®</sup> and ORPATHYS<sup>®</sup> in China and out-licensing revenue. While we are not providing net cash flow guidance for 2023, we will extend our cash runway through partnering and strategic shifting to focus on the most advanced assets from our internal development pipeline.

	2022 Actual	2023 Guidance
Oncology/Immunology consolidated revenues	\$163.8 million	\$450 – \$550 million

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 9 p.m. HKT / 1 p.m. GMT / 8 a.m. EST** – After registering, investors may access a live audio webcast of the call via HUTCHMED's website at <u>www.hutch-med.com/event/</u>.

Participants who wish to join the call and ask a question must <u>register here</u>. Upon registration, each participant will be provided with dial-in numbers and a unique PIN.

# FINANCIAL STATEMENTS

HUTCHMED will today file with the U.S. Securities and Exchange Commission its Annual Report on Form 20-F.

# 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 more than 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 drugs now approved and marketed in China. For more information, please visit: www.hutch-med.com or follow us on LinkedIn.

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### 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 consolidated subsidiaries and joint ventures unless otherwise stated or indicated by context.

#### Past Performance and Forward-Looking Statements

The performance and results of operations of the Group contained within this announcement are historical in nature, and past performance is no guarantee of future results of the Group. This announcement contains forward-looking statements within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by words like "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "pipeline," "could," "potential," "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 the COVID-19 pandemic. For further discussion of these and other risks, see HUTCHMED's filings with the U.S. Securities and Exchange Commission, on AIM and on HKEX. 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 EU law as defined in the European Union (Withdrawal) Act 2018).

# **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 960 scientists and staff (December 31, 2021: ~820), and an in-house oncology commercial organization of over 870 staff (December 31, 2021: ~630).

We have advanced 13 oncology drug candidates into clinical trials in China, with four also in active clinical development in the U.S. and Europe. Our first three drug candidates, 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 submitted for registration in Hong Kong.

# MARKETED PRODUCT SALES

#### *Fruquintinib (ELUNATE<sup>®</sup> in China)*

ELUNATE<sup>®</sup> is approved for the treatment of third-line metastatic CRC for which there is an approximate incidence of 83,000 new patients per year in China. We estimate that in 2022, approximately 32,000 (2021: approximately 22,000) new patients were treated with ELUNATE<sup>®</sup> in China resulting in in-market sales of \$93.5 million, up 32% versus 2021 (\$71.0 million). ELUNATE<sup>®</sup> surpassed regorafenib in prescription numbers for late stage CRC at the end of 2021 and that lead has continued to grow in 2022.

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<sup>®</sup> in China. We consolidate as revenues approximately 70-80% of ELUNATE<sup>®</sup> in-market sales from manufacturing fees, service fees and royalties paid to us by Lilly. In 2022, we consolidated \$69.9 million in revenue for ELUNATE<sup>®</sup>, equal to 74.8% of in-market sales.

Following negotiations with the China NHSA<sup>53</sup>, ELUNATE<sup>®</sup> continues to be included in the NRDL for a new twoyear term starting in January 2022. For this renewal, we agreed to a discount of 5% relative to the 2021 NRDL price.

In January 2022, ELUNATE<sup>®</sup> was approved in the Macau Special Administrative Region, our first drug to be approved in the territory and the first based on NMPA approval, following the latest update to the Macau provisions on new drug importation which allow drugs approved in one or more specified jurisdictions to be authorized for use in Macau.

#### Surufatinib (SULANDA<sup>®</sup> in China)

SULANDA<sup>®</sup> was launched in China in 2021 for the treatment of all advanced NETs<sup>54</sup> for which there is an approximate incidence of 34,000 new patients per year in China.

In 2021, SULANDA<sup>®</sup> was sold as a self-pay drug. We used means-tested early access and patient access programs to help patients afford SULANDA<sup>®</sup>. Despite these access programs, duration of treatment was often affected by the economic constraints of patients. Following negotiations with the China NHSA, SULANDA<sup>®</sup> was included in the NRDL starting in January 2022 at a 52% discount on our main 50mg dosage form, relative to the 2021 self-pay price. Under the NRDL, actual out-of-pocket costs for patients in 2022 represented approximately 15-20% of the 2021 self-pay price.

As a result of inclusion in the NRDL and our continued marketing activities, patient access to SULANDA<sup>®</sup>, as well as duration of treatment, have been expanding with total sales in 2022 increasing by 178% to \$32.3 million (2021: \$11.6 million). In 2022, approximately 12,000 new patients were treated with SULANDA<sup>®</sup>, representing approximately 2.5 times the approximately 4,800 new patients in 2021.

There are two therapies for advanced NETs approved and NRDL reimbursed in China: SUTENT<sup>®</sup> for the treatment of pancreatic NET (approximately 10% of NET), and AFINITOR<sup>®</sup> in broadly the same indication as SULANDA<sup>®</sup>.

In April 2022, SULANDA® was approved in the Macau Special Administrative Region.



#### Savolitinib (ORPATHYS<sup>®</sup> in China)

In late June 2021, ORPATHYS<sup>®</sup> became the first-in-class selective MET inhibitor to be approved in China. Our partner, AstraZeneca, then launched ORPATHYS<sup>®</sup> in mid-July 2021, less than three weeks after its conditional approval by the NMPA 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 and 2022, ORPATHYS<sup>®</sup> was sold as a self-pay drug. AstraZeneca introduced a patient access program in late 2021 which subsidizes use of ORPATHYS<sup>®</sup>, through progressive disease. In-market sales for ORPATHYS<sup>®</sup> grew by 159% in 2022 to \$41.2 million (2021: \$15.9m) resulting in our consolidation of \$22.3 million (2021: \$11.3m) in revenues from manufacturing fees and royalties in 2022.

Following negotiations with the China NHSA in January 2023, starting on March 1, 2023, ORPATHYS<sup>®</sup> will be included in the updated NRDL, broadening patient access to this medicine.

Market understanding of the need for MET testing has improved significantly, with ORPATHYS<sup>®</sup>'s brand share more than doubling since the end of 2021 in the rapidly growing targeted therapy area. 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<sup>®</sup> was identified as the only targeted therapy recommended for MET exon 14 patients, while similar guideline from CSCO<sup>55</sup> also recommended ORPATHYS<sup>®</sup> as the standard of care for such patients.

ORPATHYS<sup>®</sup> is the first and only selective MET inhibitor on the market in China. XALKORI<sup>®</sup> is an approved multi-kinase inhibitor of ALK and ROS1 with modest MET activity. Several selective MET inhibitors are in development in China, but none are currently expected to reach the market before 2023.

#### *Tazemetostat (TAZVERIK<sup>®</sup> in Hainan, 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.

Following inclusion in the 2022 CSCO guidelines for epithelioid carcinoma, three patients began treatment in 2022, with the first patient having remained on medication for over six months.

In December 2022, an market authorization application was submitted in Hong Kong.

#### **RESEARCH & DEVELOPMENT**

HUTCHMED announced its strategy in November 2022 aimed at accelerating its path to profitability and establishing a long-term sustainable business, by prioritizing late-stage and registrational studies to bring the most advanced drug candidates through regulatory approval as they are most likely to drive near-term value, particularly the global regulatory approvals and partnership of fruquintinib outside of China. Selected programs will be considered as candidates for out-licensing opportunities, particularly outside of China, with some early phase U.S./EU-related studies deprioritized until then, enabling the Company to focus internal resources on its later-stage drug candidates. These studies include surufatinib (outside Japan and China), amdizalisib, HMPL-760 and HMPL-306. Surufatinib, amdizalisib, HMPL-760, HMPL-306 and sovleplenib are all considered as candidates for out-licensing outside of China. HUTCHMED intends to continue to run early phase development programs for selected drug candidates in U.S., EU and Japan where we believe we can differentiate from a global perspective.

# Savolitinib (ORPATHYS<sup>®</sup> 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 over 1,500 patients to date, both as a monotherapy and in combinations.

In February 2022, a \$15 million milestone payment from AstraZeneca was triggered by the initiation of start-up activities for the SAFFRON study. In total, 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:

**MET plays an important role in NSCLC.** Savolitinib has made significant development progress in lung cancer, completing NMPA NDA review, gaining approval and successfully launching as a monotherapy in China. It is also now in multiple late stage registrational studies as a combination therapy.

The table below shows a summary of the clinical studies for savolitinib in lung cancer patients.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Savolitinib monotherapy	MET exon 14 skipping alterations	China	II Registration	Approved & launched in 2021; Final OS analysis at ELCC 2022	NCT02897479
Savolitinib monotherapy	MET exon 14 skipping alterations	China	III Confirmatory	Ongoing since 2021	NCT04923945
Savolitinib + IMFINZI®	SOUND: MET-driven, EGFR wild type	China	Ш	Ongoing since 2022	NCT05374603
Savolitinib + TAGRISSO®	<b>SAVANNAH</b> : 2L/3L EGFRm+ <sup>56</sup> ; TAGRISSO <sup>®</sup> refractory; MET+	Global	II Registration- intent	Ongoing; Data that supported Phase IIIs at WCLC 2022	NCT03778229
Savolitinib + TAGRISSO®	SAFFRON: 2L/3L EGFRm+; TAGRISSO <sup>®</sup> refractory; MET+	Global	III	Ongoing since 2022	NCT05261399
Savolitinib + TAGRISSO®	<b>SACHI</b> : 2L EGFR TKI <sup>57</sup> refractory NSCLC; MET+	China	Ш	Ongoing since 2021	NCT05015608
Savolitinib + TAGRISSO®	SANOVO: Naïve patients with EGFRm & MET+	China	Ш	Ongoing since 2021	NCT05009836

**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). Final OS and subgroup analysis was presented for this trial at ELCC 2022 and published in the journal *JTO Clinical and Research Reports*. The updated results further confirmed the favorable benefit of savolitinib in these patients and in each subgroup and the acceptable safety profile.

In addition to this trial and the confirmatory study in this patient population (NCT04923945), the SOUND Phase II trial is an open-label, interventional, multicenter, exploratory Phase II study to evaluate savolitinib combined with IMFINZI<sup>®</sup> in EGFR/ALK/ROS1 wild-type, locally advanced or metastatic NSCLC patients with MET aberrations (NCT05374603). The primary endpoint is PFS.

**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<sup>®</sup>. Among patients who experience disease progression post-TAGRISSO<sup>®</sup> 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 and SAVANNAH 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.

In January 2023, the U.S. FDA designated as a Fast Track development program the investigation of savolitinib for use in combination with TAGRISSO<sup>®</sup> 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<sup>®</sup>.

<u>SAVANNAH (NCT03778229)</u> – This global Phase II study in patients who have progressed following TAGRISSO<sup>®</sup> due to MET amplification or overexpression has three dose cohorts of savolitinib combined with TAGRISSO<sup>®</sup>. In addition to continuing TAGRISSO<sup>®</sup> treatment, patients received savolitinib 300mg QD, 300mg BID, or 600mg QD. The study reopened for enrollment to further reinforce the strength of data, initially presented at WCLC 2022. Recruitment is expected to be completed in the second half of 2023. We continue to evaluate the possibility of using the SAVANNAH study as the basis for U.S. accelerated approval.



The first presentation was at 2022 WCLC. These results were based on an analysis of 193 efficacy evaluable patients who received savolitinib 300mg once daily plus TAGRISSO<sup>®</sup> 80mg once daily at data cut-off date of August 27, 2021. Qualifying MET aberrations were FISH5+<sup>58</sup> or IHC50+<sup>59</sup>. Importantly, additional analysis using a higher cut-off level of MET aberration were presented. The higher cut-off levels for MET aberration are FISH10+<sup>60</sup> and/or IHC90+<sup>61</sup>. The prevalence of this higher cut-off levels of MET aberration was 34% of patients centrally tested for enrollment in this study versus 62% at the lower, qualifying cut-off level.

Results showed a trend toward improved response rates with increasing level of MET aberration. Across all patients in this analysis, ORR was 32% (95% CI: 26-39%), median DoR was 8.3 months (95% CI: 6.9-9.7 months), and median PFS was 5.3 months (95% CI: 4.2-5.8 months). These results are consistent with the TATTON and ORCHARD global studies. Among the 108 SAVANNAH patients who met the criteria for higher cut-off levels of MET aberration, ORR was 49% (95% CI: 39-59%), median DoR was 9.3 months (95% CI: 7.6-10.6 months), and median PFS was 7.1 months (95% CI: 5.3-8.0 months).

Importantly, among the 87 patients who did not receive prior chemotherapy, ORR was 52% (95% CI: 41-63%), median DoR was 9.6 months (95% CI: 7.6-14.9 months), and median PFS was 7.2 months (95% CI: 4.7-9.2 months). The safety profile of savolitinib plus TAGRISSO<sup>®</sup> was consistent with the known profiles of the combination and each treatment alone.

<u>SAFFRON (NCT05261399)</u> – Findings based on SAVANNAH and the TATTON studies supported the initiation of the SAFFRON global Phase III study in patients with EGFR-mutated, MET-driven, locally advanced or metastatic NSCLC whose disease progressed on first- or second-line treatment with TAGRISSO<sup>®</sup> as the most recent therapy, with no prior chemotherapy in the metastatic setting allowed. Patients are prospectively selected for the higher level of MET aberration of FISH10+ and/or IHC90+. The SAFFRON study will evaluate the efficacy and safety of savolitinib in combination with TAGRISSO<sup>®</sup> compared to pemetrexed plus platinum doublet-chemotherapy, the current standard-of-care treatment in this setting. The primary endpoint of the study is PFS. 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 <u>SANOVO</u> (NCT05009836) study in treatment naïve patients, and <u>SACHI</u> (NCT05015608) study in patients whose disease progressed following treatment with any first-line EGFR TKI. Both trials are expected to complete enrollment in 2024.

#### 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. We have conducted multiple global studies of savolitinib 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.

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% ORR 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	Ongoing since 2021; Consult CDE on registration-intent in H1 2023	NCT04923932

# Fruquintinib (ELUNATE<sup>®</sup> 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 5,000 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<sup>®</sup>, geptanolimab and tislelizumab) are underway, some of which presented encouraging data in 2021. Registration-intent studies combined with chemotherapy (FRUTIGA study in gastric cancer) or checkpoint inhibitors (TYVYT<sup>®</sup> combo, in endometrial cancer and RCC) are ongoing in China.

We are partnered with Lilly in China and have agreed to partner 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.	Ш	U.S., EU, Japan filings to complete in 2023; Results at ESMO 2022	NCT04322539
Fruquintinib monotherapy	CRC; TN <sup>62</sup> & HR+ <sup>63</sup> /Her2- <sup>64</sup> breast cancer	U.S.	I/Ib	CRC data at ASCO GI 2022. Close to completion	NCT03251378
Fruquintinib + tislelizumab (PD-1)	MSS <sup>65</sup> -CRC	U.S.	Ib/II	Ongoing since 2021; Fully enrolled; Submitting data to conference in H2 2023	NCT04577963
Fruquintinib monotherapy	<b>FRESCO</b> : ≥ 3L CRC; chemotherapy refractory	China	III	Approved and launched in 2018	NCT02314819
Fruquintinib + paclitaxel	FRUTIGA: 2L gastric cancer	China	III	Supplemental NDA to be filed in H1 2023	NCT03223376
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	CRC	China	Ш	Fully enrolled; Data at European Journal of Cancer 181 (2023) 26-37	NCT04179084
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	Endometrial cancer	China	II registration- intent	Ongoing since 2021; Ib data at CSCO 2021	NCT03903705
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	RCC	China	Ib/II	Fully enrolled; 1L & 2L data submission in 2023	NCT03903705
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	RCC	China	III	Ongoing since 2022	NCT05522231
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	Gastrointestinal tumors	China	Ib/II	Fully enrolled; Data submission in 2023	NCT03903705
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	NSCLC	China	Ib/II	Fully enrolled; Data submission in 2023 if mature	NCT03903705
Fruquintinib + TYVYT <sup>®</sup> (PD-1)	Cervical cancer	China	Ib/II	Fully enrolled; Data submission in 2023 if mature	NCT03903705
Fruquintinib + tislelizumab (PD-1)	CRC	Korea / China	Ib/II	Fully enrolled	NCT04716634

#### *Fruquintinib – CRC updates:*

<u>FRESCO-2 (NCT04322539)</u> – Positive results from this double-blind, placebo-controlled, global Phase III study in 691 patients with refractory metastatic CRC were presented at ESMO 2022. The study demonstrated that treatment with fruquintinib resulted in a statistically significant and clinically meaningful increase in OS and the key secondary endpoint of PFS compared to treatment with placebo. Specifically, the median OS was 7.4 months for the 461 patients treated with fruquintinib compared to 4.8 months for the 230 patients in the placebo group (HR 0.66; 95% CI 0.55–0.80; p<0.001). Median PFS was 3.7 months with fruquintinib compared to 1.8 months with placebo (HR 0.32; 95% CI 0.27–0.39; p<0.001). DCR was 55.5% with fruquintinib compared to 16.1% with placebo.

The safety profile of fruquintinib in FRESCO-2 was consistent with previously reported fruquintinib studies. Grade 3 or above adverse events occurred in 62.7% of patients who received fruquintinib, compared to 50.4% of patients who received placebo. Grade 3 or above adverse events that occurred in more than 5% of patients who received fruquintinib were hypertension (13.6% vs. 0.9% in the placebo group), asthenia (7.7% vs. 3.9% in the placebo group) and hand-foot syndrome (6.4% vs. 0% in the placebo group).



Filing of a rolling submission of a NDA was initiated in December 2022, and expected to be completed in the first half of 2023. MAA filing to the EMA and NDA filing to the PMDA are expected to follow in 2023.

<u>U.S. Phase I/Ib CRC cohorts (NCT03251378)</u> – Preliminary efficacy and safety data of fruquintinib in patients with refractory, metastatic CRC were presented at ASCO GI in early 2022. The study provided proof-of-concept evidence to initiate the FRESCO-2 study.

#### Fruquintinib – Gastric cancer:

<u>FRUTIGA (NCT03223376)</u> – 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, DCR and DoR. The safety profile of fruquintinib in FRUTIGA was consistent with previously reported studies. Full detailed results are subject to ongoing analysis and are expected to be disclosed at an upcoming scientific meeting.

#### Fruquintinib – Combinations with checkpoint inhibitors:

<u>Advanced endometrial cancer registration-intent cohort of TYVYT<sup>®</sup> combination (NCT03903705)</u> – Platinumbased systemic chemotherapy is the standard first-line treatment for advanced endometrial cancer. However, patients who progress following first-line chemotherapy 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. The cohort is targeting to enroll over 130 patients.

<u>Advanced metastatic renal cell carcinoma (NCT05522231)</u> – In first-line clear-cell renal cell carcinoma ("ccRCC"), 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 data disclosed at CSCO 2021 showed encouraging anti-tumor efficacy and durability in these patients.

A Phase III trial of fruquintinib in combination with TYVYT<sup>®</sup> 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 TYVYT<sup>®</sup> 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.

<u>Tislelizumab combinations (NCT04577963 & NCT04716634)</u> – In August 2021, we initiated an open-label, multicenter, non-randomized Phase Ib/II study in the U.S. to assess fruquintinib in combination with tislelizumab in patients with MSS-CRC. The Phase II study in China and Korea for fruquintinib in combination with tislelizumab is being led by BeiGene for the treatment of advanced or metastatic, unresectable CRC.

#### Fruquintinib – Exploratory development:

In China, we support an investigator initiated trial program for fruquintinib, and there are about 30 of such trials ongoing in various solid tumor settings.

#### Fruquintinib – Partnership with Takeda:

In January 2023, HUTCHMED entered into an agreement whereby Takeda will receive 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 US\$1.13 billion, including US\$400 million upfront on closing of the agreement, and up to US\$730 million in additional potential payments relating to regulatory, development and commercial sales milestones, as well as royalties on net sales. The deal is subject to customary closing conditions, including completion of antitrust regulatory reviews. Following these clearances, Takeda will become solely responsible for the development and commercialization of fruquintinib in all the included territories.

# Surufatinib (SULANDA<sup>®</sup> 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 1,200 patients to date, both as a monotherapy and in combinations, and is approved in China. HUTCHMED currently retains all rights to surufatinib worldwide.

Initial approvals for surufatinib in China are for the treatment of advanced NET patients. NETs present in the body's organ system with fragmented epidemiology. About 58% of NETs originate in the gastrointestinal tract and pancreas, 27% in the lung or bronchus, and a further 15% in other organs or unknown origins.

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.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Surufatinib monotherapy	NETs	U.S. & Europe	Ib/II Bridging	Completed	NCT02549937
Surufatinib monotherapy	NETs	Japan	Bridging	Ongoing since 2021	NCT05077384
Surufatinib + tislelizumab (PD-1)	Solid tumors	U.S. / Europe	Ib/II	Since 2021; Enrollment stopped	NCT04579757
Surufatinib monotherapy	SANET-ep: epNET <sup>66</sup>	China	III	Approved; Launched in 2021	NCT02588170
Surufatinib monotherapy	SANET-p: pNET <sup>67</sup>	China	III	Approved; Launched in 2021; Pooled analysis at ASCO 2022	NCT02589821
Surufatinib + TUOYI <sup>®</sup> (PD-1)	SURTORI-01: 2L NEC68	China	III	Ongoing since 2021	NCT05015621
Surufatinib + TUOYI <sup>®</sup> (PD-1)	NENs <sup>69</sup>	China	Π	Fully enrolled; Data at ASCO 2021 & ESMO IO <sup>70</sup> 2021	NCT04169672
Surufatinib + TUOYI <sup>®</sup> (PD-1)	Biliary tract cancer	China	II	Fully enrolled	NCT04169672
Surufatinib + TUOYI <sup>®</sup> (PD-1)	SCLC <sup>71</sup>	China	II	Ongoing since 2022	NCT05509699
Surufatinib + TUOYI <sup>®</sup> (PD-1)	Solid tumors	China	II	Fully enrolled	NCT04169672

A summary of the clinical studies of surufatinib is shown in the table below.

#### Surufatinib – Monotherapy in NET updates:

<u>U.S. NDA and EMA MAA</u> – 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. In a May 2020 pre-NDA meeting, we reached an agreement with the FDA that the two positive Phase III studies of surufatinib in patients with pNETs and epNETs in China, along with the bridging trial in the U.S. could form the basis to support a U.S. NDA submission. The FDA accepted the filing of the NDA in June 2021. However, in April 2022, we received a Complete Response Letter from the FDA regarding the NDA for surufatinib for the treatment of pNETs and epNETs. Based on interactions with the FDA and EMA, a new multi-regional clinical trial (MRCT) would be required to move forward with this program in the U.S. and Europe.

We will continue to explore conducting a multi-regional clinical trial with a partner that would support approval in U.S. and Europe.

<u>Japan Bridging Study to Support Registration for Advanced NET (NCT05077384)</u> – Based on dialogue with the Japanese PMDA, it was agreed that the Japanese NDA would include results from a 34-patient, registrationenabling bridging study in Japan to complement the existing data package. The trial was initiated in September 2021 and results are expected in the first half of 2023. We plan to engage with the PMDA when these results are available.

#### Surufatinib – Combination therapy with checkpoint inhibitors:

A Phase II China study (NCT04169672) combining surufatinib with TUOYI<sup>®</sup> 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 de-prioritized and stopped recruitment into an open-label, Phase Ib/II study of surufatinib in combination with BeiGene's tislelizumab in the U.S. and Europe. The study was to evaluate the safety, tolerability, pharmacokinetics and efficacy in patients with multiple advanced solid tumors (NCT04579757).

#### Surufatinib – Exploratory development:

In China, we support an investigator initiated trial program for surufatinib, with about 50 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.

#### Hematological Malignancies Candidates

HUTCHMED currently has six investigational drug candidates targeting hematological malignancies in clinical development. **Amdizalisib** (targeting PI3K $\delta$ ), **sovleplenib** (HMPL-523, targeting Syk) 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.

In 2021, we initiated a Phase III study in China for primary ITP, for which it has received Breakthrough Therapy Designation, and presented data on both primary ITP and hematological malignancies at ASH<sup>72</sup> 2021. HUTCHMED currently retains all rights to sovleplenib worldwide. The table below shows a summary of the clinical studies for sovleplenib.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Sovleplenib monotherapy	<b>ESLIM-01</b> : ≥ 2L ITP	China	III	Fully enrolled; Breakthrough Therapy Designation	NCT05029635
Sovleplenib monotherapy	Indolent NHL73	U.S. / Europe	I/Ib	Ongoing; Prelim. data at ASH 2021	NCT03779113
Sovleplenib monotherapy	Warm AIHA	China	II/III	Ongoing since 2022; Phase III decision in 2023 pending Phase II results	NCT05535933

<u>ESLIM-01 (Evaluation of Sovleplenib for immunological diseases–01, NCT05029635)</u> – In October 2021, we initiated a randomized, double-blinded, placebo-controlled Phase III trial in China of sovleplenib in approximately 180 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.

<u>China Phase II/III in warm AIHA</u> – This is a randomized, double-blind, placebo-controlled Phase II/III study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of sovleplenib 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 China IND was approved in July 2022. The first patient was enrolled in September 2022. The enrollment of Phase II part of the study is expected to be completed in 2023, and 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 $\delta$ , 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 medicines. The first of such activities is in combination with tazemetostat. 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; Expansion data presented at ESMO 2021	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
Amdizalisib monotherapy	Indolent NHL	U.S./ Europe	I/Ib	De-prioritized	NCT03786926

<u>Phase II registration-intent trial (NCT04849351)</u> – In April 2021, we commenced a registration-intent, singlearm, 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 is expected to complete enrollment for the marginal zone lymphoma cohort around mid-year.

#### **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.

We are developing and plan to seek approval for tazemetostat in various hematological and solid tumors, in Greater China. We are participating in Ipsen's SYMPHONY-1 (EZH-302) study, leading it in Greater China. We will generally be responsible for funding all clinical trials of tazemetostat in Greater China, including the portion of global trials conducted there. We are responsible for the research, manufacturing and commercialization of tazemetostat in Greater China.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
Tazemetostat monotherapy	Metastatic or locally advanced epithelioid sarcoma; Relapsed/refractory 3L+ follicular lymphoma	Hainan	N/A – Hainan Pilot Zone	Approved; Launched in 2022	N/A
Tazemetostat + lenalidomide + rituximab (R <sup>2</sup> )	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	NCT05467943
Tazemetostat + amdizalisib	Lymphoma sub-types	China	П	Ongoing since Feb 2023	NCT05713110

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

<u>SYMPHONY-1 (NCT04224493)</u> – This is a global, multicenter, randomized, double-blind, active-controlled, 3stage, biomarker-enriched, Phase Ib/III study of tazemetostat in combination with R<sup>2</sup> in patients with relapsed or refractory follicular lymphoma after at least one prior line of therapy. Ipsen conducted the Phase Ib portion of the study in 2021, which determined the recommended Phase III dose and also demonstrated potential efficacy in second-line follicular lymphoma. The safety profile of the combination was consistent with the previously reported safety information in the U.S. prescribing information for both tazemetostat and R<sup>2</sup>, respectively.

An interim analysis of the Phase Ib portion of the study, based on 44 follicular lymphoma patients as of June 14, 2022, was presented at ASH 2022. The safety profile of the tazemetostat and R<sup>2</sup> combination was consistent with the prescribing information for both tazemetostat and R<sup>2</sup>, respectively. Additionally, there was no clear dose response for treatment-emergent adverse events (TEAEs) or dose modifications. Of 41 evaluable patients, ORR was 97.6% with 51.2% complete response rate. Median PFS and DoR were not yet reached with a median follow-up of 11.2 months.



In the Phase III portion of the trial, approximately 500 patients are randomly assigned to receive the recommended Phase III dose of tazemetostat +  $R^2$  or placebo +  $R^2$ . The study will also include a maintenance arm with tazemetostat or placebo following the first year of treatment with tazemetostat +  $R^2$  or placebo +  $R^2$ . The first patient was enrolled in May 2022 and the first China patient was enrolled in September 2022.

<u>China Phase II bridging study in relapsed/refractory follicular lymphoma (NCT05467943)</u> – In July 2022, we initiated a multicenter, open-label, Phase II study to evaluate the efficacy, safety and pharmacokinetics of tazemetostat for the treatment of patients with relapsed/refractory follicular lymphoma intended to support conditional registration in China. The primary objective is to evaluate the efficacy of tazemetostat in patients with EZH2 mutation (Cohort 1). The secondary objectives are to evaluate the efficacy of tazemetostat in patients with EZH2 wild-type (Cohort 2) and to evaluate the safety and the pharmacokinetics of tazemetostat. Enrollment of cohort 2 is complete and cohort 1 is ongoing.

<u>China Phase II combination study in relapsed/refractory follicular lymphoma (NCT05713110)</u> – This is a multicenter, open-label, Phase II study 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-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	Ι	Ongoing since 2020; RP2D determined	NCT04272957
HMPL-306 monotherapy	Solid tumors including but not limited to gliomas, chondrosarcomas or cholangiocarcinomas	U.S.	I	Ongoing since 2021; nominate RP2D in 2023.	NCT04762602
HMPL-306 monotherapy	Hematological malignancies	U.S.	Ι	Ongoing since 2021; nominate RP2D in 2023	NCT04764474

# **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 CLL<sup>74</sup> 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 <sup>75</sup> , other B-NHL	China	I	Ongoing since Jan 2022	NCT05190068	
HMPL-760 monotherapy	CLL, SLL, other NHL	U.S.	I	De-prioritized	NCT05176691	

#### **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; Data submission planned in 2023; Preparing registration study	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

After consultation with the CDE, a monotherapy registration trial design has been agreed, and preparations are underway.

### **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. A China Phase I study was initiated in July 2021. 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 combined with immuno-oncology or other therapeutic agents. 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)  $\alpha$  and disrupts the "do not eat me" signal that cancer cells use to shield themselves from the immune system. HUTCHMED currently retains all rights to HMPL-A83 worldwide.

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.

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

# Immunology Collaboration with Inmagene

In January 2021, we entered into a strategic partnership with Inmagene, a clinical development stage company with a focus on immunological diseases, to further develop four novel preclinical drug candidates we discovered for the potential treatment of multiple immunological diseases. Under the terms of the agreement, we granted Inmagene exclusive options to such drug candidates solely for the treatment of immunological diseases. Funded by Inmagene, we work together to move the drug candidates towards IND. If successful, Inmagene



will then advance the drug candidates through global clinical development. INDs for the first two compounds were submitted in 2022.

Treatment	Name, Line, Patient Focus	Sites	Phase	Status/Plan	NCT #
IMG-007 (OX40 monoclonal antibody)	Healthy volunteers; adults with moderate to severe atopic dermatitis	Global	I	Ongoing since 2022	NCT05353972
IMG-004 (BTK inhibitor)	Healthy volunteers	Global	I	Ongoing since 2022	NCT05349097

<u>*IMG-007 in atopic dermatitis*</u> – 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. The Phase I study in healthy volunteers was initiated in July 2022 in Australia.

<u>IMG-004 in immunological diseases</u> – This is a non-covalent, reversible small molecule inhibitor targeting BTK. Designed specifically for inflammatory and autoimmune diseases that usually require long-term treatment, IMG-004 is potent, highly selective and brain permeable. The Phase I study in healthy volunteers in the U.S. was initiated in August 2022.

#### MANUFACTURING

We continue to use contract manufacturing organizations in China to produce our clinical and commercial API<sup>76</sup> 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 are building a new drug product facility in Pudong, Shanghai, which will increase our novel drug product manufacturing capacity by over five times. The construction and qualification of the Shanghai facility is expected to be completed in mid-2023 and technology transfer will start for some projects into the facility in late 2023. We expect to manufacture 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 sovleplenib into the selected commercial manufacturing facilities in preparation for potential NDA filings. Process validation for these products (both API and drug product) is expected to complete in 2023.

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 has been completed, and process validation for drug product will be completed in the second half of 2023 in time for potential approval and launch.



# **OTHER VENTURES**

Our Other Ventures include drug marketing and distribution platforms covering about 290 cities and towns in China with over 2,900 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 2022, our Other Ventures delivered encouraging growth with consolidated revenues up 11% (15% at CER) to \$262.6 million (2021: \$236.5m). Consolidated net income attributable to HUTCHMED from our Other Ventures increased by 16% (17% at CER) to \$54.6 million (2021: \$47.3m, excluding net income attributable to HUTCHMED of \$7.1m contributed from HBYS which was disposed in September 2021; \$82.9m from the divestment of HBYS and \$5.6m from land compensation, before withholding tax).

**Hutchison Sinopharm**<sup>77</sup>: 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 16% (21% at CER) to \$237.3 million in 2022 (2021: \$204.1m).

In 2021, the Hong Kong International Arbitration Centre made a final award in favor of Hutchison Sinopharm against Luye<sup>78</sup> in the amount of RMB253.2 million (\$36.4 million), plus costs and interest (the "Award"), in connection with the termination of Hutchison Sinopharm's right to distribute SEROQUEL<sup>®</sup> 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 October 7, 2022, Luye filed a Notice of Appeal to the Court of Appeal regarding the dismissal and was accepted on November 8, 2022. A Court of Appeal hearing date has been set for June 2023.

**SHPL:** Our own-brand prescription drugs business, operated through our non-consolidated joint venture SHPL, grew sales by 11% (14% at CER) to \$370.6 million (2021: \$332.6m). This sales growth and favorable product mix led to an increase of 12% (13% at CER) in net income attributable to HUTCHMED to \$49.9 million (2021: \$44.7m).

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.

*SXBX*<sup>79</sup> *pill*: SHPL's main product is SXBX pill, an oral vasodilator prescription therapy for coronary artery disease. SXBX pill is the third largest botanical prescription drug in this indication in China, with a national market share in January to December 2022 of 21.0% (2021: 19.6%). Sales increased by 11% (14% at CER) to \$341.6 million in 2022 (2021: \$307.1m).

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 China.

We continue to review divestment and equity capital market options and we have started the process for a share reform of the SHPL joint venture.

*Dividends:* Our share of SHPL's profits are passed to the HUTCHMED Group through dividend payments. In 2022, dividends of \$43.7 million (2021: \$49.9m) were paid from SHPL to the HUTCHMED Group level with aggregate dividends received by HUTCHMED since inception of over \$280 million.

Weiguo Su Chief Executive Officer and Chief Scientific Officer February 28, 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 shortterm 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-toperiod 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 used in operating activities to Adjusted Group net cash flows excluding financing activities:

\$'millions	2022	2021
Net cash used in operating activities	(268.6)	(204.2)
Net cash generated from/(used in) investing activities	296.6	(306.3)
Effect of exchange rate changes on cash and cash equivalents	(9.5)	2.4
Excludes: Deposits in short-term investments	1,202.0	1,356.0
Excludes: Proceeds from short-term investments	(1,518.4)	(921.4)
Adjusted Group net cash flows excluding financing activities	(297.9)	(73.5)

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

\$'millions (except %)	Year I	Ended	Cha	ange Amo	ount	Change %		
	December 31, 2022	December 31, 2021	Actual	CER	Exchange effect	Actual	CER	Exchange effect
Consolidated revenues								
— Oncology/Immunology	163.8	119.6	44.2	48.9	(4.7)	37%	41%	-4%
— Other Ventures^	262.6	236.5	26.1	36.4	(10.3)	11%	15%	-4%
^ Includes:								
— Hutchison Sinopharm — prescription drugs	237.3	204.1	33.2	43.2	(10.0)	16%	21%	-5%
Non-consolidated joint venture revenues								
— SHPL	370.6	332.6	38.0	47.1	(9.1)	11%	14%	-3%
— SXBX pill	341.6	307.1	34.5	42.7	(8.2)	11%	14%	-3%
Consolidated net income attributable to HUTCHMED								
- Other Ventures	54.6	142.9	(88.3)	(87.7)	. ,	-62%	-61%	
- Consolidated entities	4.7		2.1	2.3	(- )	86%	89%	
— Equity investees	49.9	140.3	(90.4)	(90.0)	( )	-64%	-64%	-
— SHPL	49.9	44.7	5.2	5.6	(- )	12%	13%	
— HBYS (Note)	-	95.6	(95.6)	(95.6)	-	-100%	-100%	-
Excludes net income attributable to HUTCHMED contributed from HBYS and one-time gains								
— Other Ventures	54.6	47.3	7.3	7.9	(0.6)	16%	17%	-1%
— Consolidated entities	4.7	2.6	2.1	2.3	(0.2)	86%	89%	-3%
— Equity investees	49.9	44.7	5.2	5.6	(0.4)	12%	13%	-1%
— SHPL	49.9	44.7	5.2	5.6	(0.4)	12%	13%	-1%

Note: On September 28, 2021, the Group completed the divestment of HBYS and the net income attributable to HUTCHMED contributed from HBYS was \$7.1 million for the period ended September 28, 2021. For the year ended December 31, 2021, one-time gains include gain on divestment of \$82.9 million and land compensation gain of \$5.6 million.



# **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.

Our Oncology/Immunology operations have historically not generated significant profits and have operated at a net loss, as creating potential global first-in-class or best-in-class drug candidates requires a significant investment of resources over a prolonged period of time. As such, we incurred net losses of \$360.8 million for the year ended December 31, 2022 and net losses of \$194.6 million for the year ended December 31, 2021.

As of December 31, 2022, we had cash and cash equivalents and short-term investments of \$631.0 million and unutilized bank facilities of \$140.3 million. As of December 31, 2022, we had \$18.1 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 \$318,000 and \$89,000 for the years ended December 31, 2022 and 2021, 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 December 31, 2022.

In addition, our non-consolidated joint venture, SHPL, held an aggregate of \$33.9 million in cash and cash equivalents and no bank borrowings as of December 31, 2022. 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**

	Year Ended December 31,	
	2022	2021
	(in \$'000	))
Cash Flow Data:		
Net cash used in operating activities	(268,599)	(204,223)
Net cash generated from/(used in) investing activities	296,588	(306,320)
Net cash (used in)/generated from financing activities	(82,763)	650,028
Net (decrease)/increase in cash and cash equivalents	(54,774)	139,485
Effect of exchange rate changes	(9,490)	2,427
Cash and cash equivalents at beginning of the year	377,542	235,630
Cash and cash equivalents at end of the year	313,278	377,542

#### Net Cash used in Operating Activities

Net cash used in operating activities was \$204.2 million for the year ended December 31, 2021, compared to net cash used in operating activities of \$268.6 million for the year ended December 31, 2022. The net change of \$64.4 million was primarily attributable to higher operating expenses of \$149.7 million from \$684.4 million for the year ended December 31, 2022. The foregoing was partially offset by an increase in revenue of \$70.3 million from \$356.1 million for the year ended December 31, 2022. The foregoing was partially offset by an increase in revenue of \$70.3 million from \$356.1 million for the year ended December 31, 2021 to \$426.4 million for the year ended December 31, 2022 and an increase in changes of working capital of



\$26.2 million from \$32.5 million for the year ended December 31, 2021 to \$58.7 million for the year ended December 31, 2022.

#### Net Cash generated from/(used in) Investing Activities

Net cash used in investing activities was \$306.3 million for the year ended December 31, 2021, compared to net cash generated from investing activities of \$296.6 million for the year ended December 31, 2022. The net change of \$602.9 million was primarily attributable to short-term investments which had net deposits of \$434.6 million for the year ended December 31, 2022. The net change was partially offset by the proceeds received from divestment of an equity investee of \$159.1 million during the year ended December 31, 2022, compared to a dividend of \$16.5 million received from divestment of the same equity investee during the year ended December 31, 2022.

#### Net Cash (used in)/generated from Financing Activities

Net cash generated from financing activities was \$650.0 million for the year ended December 31, 2021, compared to net cash used in financing activities of \$82.8 million for the year ended December 31, 2022. The net change of \$732.8 million was mainly attributable to net proceeds from issuances of shares of \$685.4 million from a private placement in April 2021 and our public offering on the HKEX with over-allotment option exercised in full in June and July, 2021. The net change was also attributable to an increase in purchases of ADSs of \$20.8 million by a trustee for the settlement of equity awards of the Company which totaled \$27.3 million for the year ended December 31, 2022, as well as an increase in dividends paid to non-controlling shareholders of subsidiaries of \$15.7 million from \$9.9 million for the year ended December 31, 2021.

### LOAN FACILITIES

In May 2019, our subsidiary entered into a credit facility arrangement with HSBC<sup>80</sup> for the provision of unsecured credit facilities in the aggregate amount of HK\$400.0 million (\$51.3 million). The 3-year credit facilities include (i) a HK\$210.0 million (\$26.9 million) term loan facility and (ii) a HK\$190.0 million (\$24.4 million) revolving loan facility, both with an interest rate at HIBOR<sup>81</sup> plus 0.85% per annum. These credit facilities are guaranteed by us and include certain financial covenant requirements. The term loan was drawn in October 2019 and was repaid in May 2022. The revolving loan facility also expired in May 2022.

In August 2020, our subsidiary entered into a 24-month revolving loan facility with Deutsche Bank AG<sup>82</sup> in the amount of HK\$117.0 million (\$15.0 million) with an interest rate at HIBOR plus 4.5% per annum. This revolving facility is guaranteed by us and includes certain financial covenant requirements. The revolving loan facility expired in August 2022.

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 (\$108.4 million) with an annual interest rate at the 5-year China Loan Prime Rate less 0.80% (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 December 31, 2022, RMB126.1 million (\$18.1 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 HIBOR plus 0.5% per annum. This revolving facility is guaranteed by us. As of December 31, 2022, no amount was drawn from the revolving loan facility.

Our non-consolidated joint venture SHPL had no bank borrowings outstanding as of December 31, 2022.

#### CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table sets forth our contractual obligations as of December 31, 2022. 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.

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Bank borrowings	18,104	_	360	1,918	15,826
Interest on bank borrowings	4,294	318	1,273	1,200	1,503
Purchase obligations	22,130	20,323	1,807	-	_
Lease obligations	10,122	4,498	4,149	1,360	115
	54,650	25,139	7,589	4,478	17,444

#### SHPL

The following table sets forth the contractual obligations of our non-consolidated joint venture SHPL as of December 31, 2022. 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.

	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Purchase obligations	1,307	1,307			
Lease obligations	2,243	826	1,417	_	_
	3,550	2,133	1,417		

# 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. 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. In general, our exposure to foreign exchange risks is limited.

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 PBOC<sup>83</sup>. 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 net loss of a 1.0% interest rate shift would be a maximum increase/decrease of \$0.1 million for the year ended December 31, 2022.

### **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 15 to the full year 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 2.8% as of December 31, 2022, an increase from 2.6% as of December 31, 2021. The increase was primarily attributable to the decrease in equity due to the increase in net loss during the year.

#### SIGNIFICANT INVESTMENTS HELD

Except for our investment in a non-consolidated joint venture SHPL with a carrying value of \$73.5 million including details below and those as disclosed in note 11 to the full year financial statements, we did not hold any other significant investments in the equity of any other companies as of December 31, 2022.

Place of establishment	Nominal Value of	Equity Interest	Principal activities	
and operations	Registered Capital	Attributable to the Group		
PRC	(in RMB'000) 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 year ended December 31, 2022 were \$43.7 million.

#### FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

Note 15 to the full year financial statements discloses our planned expenditures on capital assets as of December 31, 2022. 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 year ended December 31, 2022, 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. RMB126.1 million (\$18.1 million) was utilized from the fixed asset loan facility as of December 31, 2022.



# 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 0.2%, 1.5% and 1.8% in 2020, 2021 and 2022, 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.

### FINAL DIVIDEND

The Board does not recommend any final dividend for the year ended December 31, 2022.



# **OTHER INFORMATION**

### **CORPORATE STRATEGY**

The primary objective of the Company and its subsidiaries (the "Group") is to become 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 to develop and expand its drug candidate portfolio for the global market, building on the first-mover advantage in the development and launch of novel cancer drugs in China, and engaging partners for late-stage development and commercialization outside China. This is aligned with the Company's culture of innovation and high engagement and empowerment with a high 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 sustainability and delivering business solutions that support transition to net-zero carbon emissions. Further information on the sustainability initiatives of the Group and its key relationships with stakeholders can also be found in the standalone sustainability report of the Group.

### **HUMAN RESOURCES**

As at December 31, 2022, the Group employed approximately 2,030 (December 31, 2021: ~1,760) full time staff members. Staff costs for the year ended December 31, 2022, including directors' emoluments, totaled \$227.2 million (2021: \$180.2 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**

As an innovative, commercial-stage biopharmaceutical company, the Company embraces sustainability at the core of how it operates. Over the past two decades and on an ongoing basis, the Company is working hard to contribute to the enhancement of healthcare systems by continuously providing quality and accessible drugs. As the world adapted to the changes brought about by the COVID-19 pandemic, it has highlighted the importance of incorporating sustainability factors into our strategy. The Company embarked on its sustainability journey in 2020 by making voluntary disclosures in its inaugural sustainability report to demonstrate its efforts, and establishing a board level Sustainability Committee in 2021 to support the Board of Directors (the "Board") in fulfilling their responsibilities. The second sustainability report for 2021, with enhanced disclosures, was published in May 2022 and the third sustainability report for 2022 will be published alongside our 2022 Annual Report in due course.

Over the course of 2022, we have rolled out a number of substantial sustainability initiatives, including renewing our focus on sustainability material topics with the engagement of stakeholders, establishing 11 short- to long-term sustainability goals and targets, stepping up efforts in sustainability governance by establishing a four-tier governance framework to facilitate oversight and implementation of sustainability issues within the Company, having sustainability KPIs on goals and targets incorporated to management's performance and remunerations, and conducting our first climate-related risk assessment. The Company believes that all these efforts will guide it towards a more sustainability initiatives and their performance.

#### **CLOSURE OF REGISTER OF MEMBERS**

The register of members of the Company will be closed from Tuesday, May 9, 2023 to Friday, May 12, 2023, both days inclusive, during which period no transfer of shares will be effected, to determine shareholders' entitlement to attend and vote at the 2023 Annual General Meeting (or at any adjournment or postponement thereof). All share certificates with completed transfer forms, either overleaf or separately, must be lodged with (a) the Hong Kong Branch Share Registrar of the Company, Computershare Hong Kong Investor Services

Limited, at Rooms 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong or (b) the Principal Share Registrar of the Company, Computershare Investor Services (Jersey) Limited c/o Computershare Investor Services PLC, The Pavilions, Bridgwater Road, Bristol, BS99 6ZY, United Kingdom, no later than 4:30 pm Hong Kong time on Monday, May 8, 2023.

# PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

During the year ended December 31, 2022, 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 Group 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 year ended December 31, 2022 with all code provisions of the Hong Kong Corporate Governance Code contained in Appendix 14 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (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 their compliance with the required standards set out in such code regarding their securities transactions throughout their tenure during the year ended December 31, 2022.

#### ANNUAL GENERAL MEETING

The Annual General Meeting of the Company will be held on Friday, May 12, 2023. Notice of the 2023 Annual General Meeting will be published and issued to shareholders in due course.

# 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 and offering 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 issued by the Company dated June 18, 2021 is as below:



Use of Proceeds	Percentage of Total Net Proceeds	Approximate Amount	Actual Usage up to December 31, 2022	Unutilized Net Proceeds as of December 31, 2022	Expected Timeline for Utilization of Proceeds (note)
	(%)	(\$'millions)	(\$'millions)	(\$'millions)	
Advance our late-stage clinical programs for savolitinib, surufatinib, fruquintinib, amdizalisib and sovleplenib 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	81.7	35.4	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	32.4	55.4	2023
Working capital, expanding internal capabilities globally and in China and general corporate purposes	5%	29.1	29.1	-	Fully utilized
	100%	585.2	494.4	90.8	

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.

#### AUDIT REPORT ON THE ANNUAL FINANCIAL STATEMENTS

The consolidated financial statements of the Company and its subsidiary companies for the year ended December 31, 2022 prepared in accordance with accounting principles generally accepted in the U.S. have been audited by the Company's auditors, PricewaterhouseCoopers. The consolidated financial statements of the Company and its subsidiary companies for the year ended December 31, 2022 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 December 31, 2022 and up to the date of this announcement.

#### PUBLICATION OF FULL YEAR RESULTS AND ANNUAL REPORT

This full year results announcement is published on the websites of HKEX (<u>www.hkexnews.hk</u>), the U.S. Securities and Exchange Commission (<u>www.sec.gov/edgar</u>), the London Stock Exchange (<u>www.londonstockexchange.com</u>) and the Company (<u>www.hutch-med.com</u>). The annual report of the Group for the year ended December 31, 2022 will be published on the websites of HKEX and the Company, and dispatched to the Company's shareholders in due course.

#### **REFERENCES & ABBREVIATIONS**

<sup>&</sup>lt;sup>1</sup> Takeda = Takeda Pharmaceuticals International AG.

<sup>&</sup>lt;sup>2</sup> CRC = Colorectal cancer.

<sup>&</sup>lt;sup>3</sup> ESMO = European Society for Medical Oncology.

<sup>&</sup>lt;sup>4</sup> NDA = New Drug Application.

<sup>&</sup>lt;sup>5</sup> FDA = Food and Drug Administration.

<sup>&</sup>lt;sup>6</sup> PFS = Progression-free survival.

<sup>&</sup>lt;sup>7</sup> MET = Mesenchymal epithelial transition factor.



<sup>8</sup> NSCLC = Non-small cell lung cancer.

<sup>9</sup> NRDL = National Reimbursement Drug List.

- <sup>10</sup> We also report changes in performance at constant exchange rate ("CER") which is a non-GAAP measure. Please refer to "Use of Non-GAAP Financial Measures and Reconciliation" below for further information relevant to the interpretation of these financial measures and reconciliations of these financial measures to the most comparable GAAP measures.
- <sup>11</sup> In-market sales = total sales to third parties provided by Eli Lilly (ELUNATE®), AstraZeneca (ORPATHYS®) and HUTCHMED (ELUNATE®, SULANDA® and TAZVERIK®)
- <sup>12</sup> AstraZeneca = AstraZeneca AB (publ), a wholly-owned subsidiary of AstraZeneca PLC.
- <sup>13</sup> R&D = Research and development.
- <sup>14</sup> Lilly = Eli Lilly and Company.
- <sup>15</sup> ITP = Immune thrombocytopenia purpura.
- <sup>16</sup> NMPA = National Medical Products Administration.
- <sup>17</sup> EMA = European Medicines Agency.
- <sup>18</sup> PMDA = Pharmaceuticals and Medical Devices Agency.
- <sup>19</sup> MAA = Marketing Authorization Application.
- <sup>20</sup> EGFR = Epidermal growth factor receptor.
  <sup>21</sup> WCLC = World Conference on Lung Cancer.
- <sup>22</sup> ORR = Objective response rate.
- <sup>23</sup> DoR = Duration of response.
- <sup>24</sup> OS = Overall survival.
- <sup>25</sup> ELCC = European Lung Cancer Congress.
- <sup>26</sup> PRCC = Papillary renal cell carcinoma.
- <sup>27</sup> VEGFR = Vascular endothelial growth factor receptor.
- <sup>28</sup> ASCO GI = ASCO (American Society of Clinical Oncology) Gastrointestinal Cancers Symposium.
- <sup>29</sup> DCR = Disease control rate.
- <sup>30</sup> PD-1 = Programmed cell death protein-1.
- <sup>31</sup> RCC = Renal cell carcinoma.
- <sup>32</sup> FGFR = Fibroblast growth factor receptor.
- <sup>33</sup> CSF-1R = Colony-stimulating factor 1 receptor.
- <sup>34</sup> ASCO = American Society of Clinical Oncology.
- <sup>35</sup> NANETS = North American Neuroendocrine Tumor Society Medical Symposium.
- <sup>36</sup> Syk = Spleen tyrosine kinase.
- <sup>37</sup> AIHA = autoimmune hemolytic anemia.
- <sup>38</sup> PI3Kδ = Phosphoinositide 3-kinase delta.
- <sup>39</sup> Ipsen = Ipsen SA, parent of Epizyme Inc.
- <sup>40</sup> Epizyme = Epizyme Inc., a wholly owned subsidiary of Ipsen SA.
- <sup>41</sup> IDH = Isocitrate dehydrogenase.
- <sup>42</sup> BTK = Bruton's tyrosine kinase.
- <sup>43</sup> ERK = Extracellular signal-regulated kinase.
- <sup>44</sup> MAPK pathway = RAS-RAF-MEK-ERK signaling cascade.
- <sup>45</sup> CDE = Center for Drug Evaluation
- <sup>46</sup> IHCC = Intrahepatic cholangiocarcinoma.
- <sup>47</sup> SHPL = Shanghai Hutchison Pharmaceuticals Limited.
- <sup>48</sup> HBYS = Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited.
- <sup>49</sup> GAAP = Generally Accepted Accounting Principles.
- <sup>50</sup> HKEX = The Main Board of The Stock Exchange of Hong Kong Limited.
- <sup>51</sup> ADS = American depositary share.
- <sup>52</sup> SG&A Expenses = selling, general and administrative expenses.
- <sup>53</sup> NHSA = China National Healthcare Security Administration.
- <sup>54</sup> NET = Neuroendocrine tumor.
- <sup>55</sup> CSCO = Chinese Society of Clinical Oncology.
- <sup>56</sup> EGFRm+ = Epidermal growth factor receptor mutated.
- <sup>57</sup> TKI = Tyrosine kinase inhibitor.
- <sup>58</sup> FISH5+ = MET amplification as detected by FISH with MET copy number ≥ 5 and/or MET: CEP signal ratio ≥ 2.
- <sup>59</sup> IHC50+ = MET overexpression as detected by IHC with 3+ in ≥ 50% tumor cells.
- <sup>60</sup> FISH10+ = MET amplification as detected by FISH with MET copy number ≥ 10.
- <sup>61</sup> IHC90+ = MET overexpression as detected by IHC with 3+ in ≥ 90% tumor cells.
- 62 TN = Triple negative.
- <sup>63</sup> HR+ = Hormone receptor positive.
- <sup>64</sup> Her2- = Human epidermal growth factor receptor 2 negative.
- <sup>65</sup> MSS = Microsatellite Stable.
- <sup>66</sup> epNET = extra-pancreatic neuroendocrine tumor.
- <sup>67</sup> pNET= pancreatic neuroendocrine tumor.
- 68 NEC = Neuroendocrine carcinoma
- <sup>69</sup> NEN = Neuroendocrine neoplasms.
- <sup>70</sup> IO = Immuno-oncology.
- <sup>71</sup> SCLC = Small cell lung cancer.
- <sup>72</sup> ASH = American Society of Hematology.
- 73 NHL = Non-Hodakin's Lymphoma.
- <sup>74</sup> CLL = Chronic lymphocytic leukemia.
- <sup>75</sup> SLL = Small lymphocytic lymphoma.
- <sup>76</sup> API = Active pharmaceutical ingredient.
- 77 Hutchison Sinopharm = Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited.
- <sup>78</sup> Luye = Luye Pharma Hong Kong Ltd.
- 79 SXBX = She Xiang Bao Xin.
- <sup>80</sup> HSBC = The Hongkong and Shanghai Banking Corporation Limited.
- <sup>81</sup> HIBOR = Hong Kong Interbank Offered Rate.
- <sup>82</sup> Deutsche Bank AG = Deutsche Bank AG, Hong Kong Branch.
- <sup>83</sup> PBOC = People's Bank of China.

# **CONSOLIDATED FINANCIAL STATEMENTS**

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

		Decemb	er 31,
	Note	2022	2021
Assets			
Current assets			
Cash and cash equivalents	5	313,278	377,542
Short-term investments	5	317,718	634,158
Accounts receivable	6	97,988	83,580
Other receivables, prepayments and deposits	7	54,214	81,041
Inventories	8	56,690	35,755
Total current assets		839,888	1,212,076
Property, plant and equipment	9	75,947	41,275
Right-of-use assets	10	8,722	11,879
Deferred tax assets	24(ii)	15,366	9,401
Investments in equity investees	11	73,777	76,479
Other non-current assets		15,745	21,551
Total assets		1,029,445	1,372,661
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	12	71,115	41,177
Other payables, accruals and advance receipts	13	264,621	210,839
Bank borrowings	14	_	26,905
Income tax payable	24(iii)	1,112	15,546
Other current liabilities		17,055	17,191
Total current liabilities		353,903	311,658
Lease liabilities	10	5,196	7,161
Deferred tax liabilities	24(ii)	2,710	2,765
Long-term bank borrowings	14	18,104	—
Other non-current liabilities		12,662	11,563
Total liabilities		392,575	333,147
Commitments and contingencies	15		
Company's shareholders' equity			
Ordinary shares; \$0.10 par value; 1,500,000,000 shares			
authorized; 864,775,340 and 864,530,850 shares issued at			
December 31, 2022 and 2021 respectively	16	86,478	86,453
Additional paid-in capital		1,497,273	1,505,196
Accumulated losses		(971,481)	(610,328)
Accumulated other comprehensive (loss)/income		(1,903)	5,572
Total Company's shareholders' equity		610,367	986,893
Non-controlling interests		26,503	52,621
Total shareholders' equity		636,870	1,039,514
Total liabilities and shareholders' equity		1,029,445	1,372,661
	-		

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

		Year Ended December 31,			
	Note	2022	2021	2020	
Revenues					
Goods —third parties		314,329	266,199	203,606	
-related parties	23(i)	5,293	4,256	5,484	
Services —commercialization—third parties		41,275	27,428	3,734	
—collaboration research and					
development					
—third parties		23,741	18,995	9,771	
—research and development					
-related parties	23(i)	507	525	491	
Other collaboration revenue					
-royalties-third parties		26,310	15,064	4,890	
—licensing—third parties		14,954	23,661	—	
Total revenues	18	426,409	356,128	227,976	
Operating expenses					
Costs of goods—third parties		(268,698)	(229,448)	(178,828)	
Costs of goods—related parties		(3,616)	(3,114)	(3,671)	
Costs of services—commercialization —		. ,		. ,	
third parties		(38,789)	(25,672)	(6,020)	
Research and development expenses	20	(386,893)	(299,086)	(174,776)	
Selling expenses		(43,933)	(37,827)	(11,334)	
Administrative expenses		(92,173)	(89,298)	(50,015)	
Total operating expenses		(834,102)	(684,445)	(424,644)	
		(407,693)	(328,317)	(196,668)	
Gain on divestment of an equity investee	22	_	121,310	_	
Other (expense)/income					
Interest income	26	9,599	2,076	3,236	
Other income		1,833	2,426	4,600	
Interest expense	26	(652)	(592)	(787)	
Other expense		(13,509)	(12,643)	(115)	
Total other (expense)/income		(2,729)	(8,733)	6,934	
Loss before income taxes and equity in				·	
earnings of equity investees		(410,422)	(215,740)	(189,734)	
Income tax benefit/(expense)	24(i)	283	(11,918)	(4,829)	
Equity in earnings of equity investees, net of tax	11	49,753	60,617	79,046	
Net loss		(360,386)	(167,041)	(115,517)	
Less: Net income attributable to non-controlling		(,,	(,,	(,,	
interests		(449)	(27,607)	(10,213)	
Net loss attributable to the Company		(360,835)	(194,648)	(125,730)	
Losses per share attributable to the Company—			(101,010)	(1=0,100)	
basic and diluted (US\$ per share)	25	(0.43)	(0.25)	(0.18)	
Number of shares used in per share calculation—	20	(010)	(0.20)	(0.10)	
basic and diluted	25	847,143,540	792,684,524	697,931,437	

# HUTCHMED (CHINA) LIMITED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (IN US\$'000)

	Year Ended December 31,			
	2022	2021	2020	
Net loss	(360,386)	(167,041)	(115,517)	
Other comprehensive (loss)/income				
Foreign currency translation (loss)/gain	(8,469)	2,964	9,530	
Total comprehensive loss	(368,855)	(164,077)	(105,987)	
Less: Comprehensive loss/(income) attributable to non-				
controlling interests	545	(28,029)	(11,413)	
Total comprehensive loss attributable to the Company	(368,310)	(192,106)	(117,400)	

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# HUTCHMED (CHINA) LIMITED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (IN US\$'000, EXCEPT SHARE DATA IN '000)

	Ordinary Shares Number	Ordinary Shares Value	Additional Paid-in Capital	Accumulated Losses	Accumulated Other Comprehensive (Loss)/Income	Total Company's Shareholders' Equity	Non- controlling Interests	Total Shareholders' Equity
As at January 1, 2020	666,906	66,691	514,904	(289,734)	(3,849)	288,012	24,891	312,903
Net (loss)/income	_	—	—	(125,730)	—	(125,730)	10,213	(115,517)
Issuance in relation to public offering	23,669	2,366	115,975	_	—	118,341	—	118,341
Issuances in relation to private investment in public equity ("PIPE")	36,667	3,667	196,333	_	_	200,000	_	200,000
Issuance costs	—	—	(8,317)	—	—	(8,317)	—	(8,317)
Issuances in relation to share option exercises	480	48	545	_	—	593	—	593
Share-based compensation								
Share options	—	—	8,727	—	—	8,727	10	8,737
Long-term incentive plan ("LTIP")	—	—	7,203	—	—	7,203	16	7,219
	_		15,930	_		15,930	26	15,956
LTIP—treasury shares acquired and held by Trustee	_	_	(12,904)	_	_	(12,904)	_	(12,904)
Dividends declared to non-controlling shareholders of subsidiaries	_	_	_	_	—	_	(1,462)	(1,462)
Purchase of additional interests in a subsidiary of an equity investee (Note 11)	_	_	(52)	(83)	(4)	(139)	(35)	(174)
Transfer between reserves	—	—	44	(44)	—	—	_	-
Foreign currency translation adjustments		_	_		8,330	8,330	1,200	9,530
As at December 31, 2020	727,722	72,772	822,458	(415,591)	4,477	484,116	34,833	518,949
Net (loss)/income	_			(194,648)		(194,648)	27,607	(167,041)
Issuance in relation to public offering	119,600	11,960	602,907	_	—	614,867	—	614,867
Issuance in relation to PIPE	16,393	1,639	98,361	_	_	100,000	—	100,000
Issuance costs	—	_	(29,806)	_	_	(29,806)	_	(29,806)
Issuances in relation to share option exercises	816	82	2,370	_	—	2,452	—	2,452
Share-based compensation								
Share options	—	—	16,339	—	—	16,339	26	16,365
LTIP			19,808			19,808	70	19,878
	—	—	36,147	_	—	36,147	96	36,243
LTIP—treasury shares acquired and held by Trustee	_	_	(27,309)	_	_	(27,309)	_	(27,309)
Dividends declared to non-controlling shareholders of subsidiaries	_	_	_	_	_	_	(9,894)	(9,894)
Transfer between reserves	—	—	89	(89)	—	—	_	-
Divestment of an equity investee (Note 22)	_	_	(21)	_	(1,447)	(1,468)	(443)	(1,911)
Foreign currency translation adjustments		_		_	2,542	2,542	422	2,964
As at December 31, 2021	864,531	86,453	1,505,196	(610,328)	5,572	986,893	52,621	1,039,514
Net (loss)/income	_	_		(360,835)		(360,835)	449	(360,386)
Issuances in relation to share option exercises	244	25	149	—	—	174	—	174
Share-based compensation								
Share options	_	—	6,724	_	—	6,724	12	6,736
LTIP	—	—	32,970	—	—	32,970	15	32,985
	_	_	39,694	_		39,694	27	39,721
LTIP—treasury shares acquired and held by Trustee	_	_	(48,084)	_	_	(48,084)	_	(48,084)
Dividends declared to non-controlling shareholders of subsidiaries	_	_	_	_	_	_	(25,600)	(25,600)
Transfer between reserves	_	—	318	(318)	-	_	_	_
Foreign currency translation adjustments	_		_		(7,475)	(7,475)	(994)	(8,469)
As at December 31, 2022	864,775	86,478	1,497,273	(971,481)	(1,903)	610,367	26,503	636,870

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

		Year Ended December 31,		
	Note	2022	2021	2020
Net cash used in operating activities	27	(268,599)	(204,223)	(62,066)
Investing activities				
Purchases of property, plant and equipment		(36,664)	(16,401)	(7,949)
Purchase of leasehold land		—	(355)	(11,631)
Refund/(payment) of leasehold land deposit		—	930	(2,326)
Deposits in short-term investments		(1,202,013)	(1,355,976)	(732,908)
Proceeds from short-term investments		1,518,453	921,364	629,373
Purchase of a warrant	19	—	(15,000)	—
Dividend and proceeds received from divestment of				
Hutchison Whampoa Guangzhou Baiyunshan Chinese				
Medicine Company Limited ("HBYS")	22	16,488	159,118	—
Deposit received for divestment of other equity investee	11	324	—	
Net cash generated from/(used in) investing activities		296,588	(306,320)	(125,441)
Financing activities				
Proceeds from issuances of ordinary shares		174	717,319	318,934
Purchases of treasury shares	17(ii)	(48,084)	(27,309)	(12,904)
Dividends paid to non-controlling shareholders of				
subsidiaries		(25,600)	(9,894)	(1,462)
Repayment of loan to a non-controlling shareholder of a				
subsidiary		—	(579)	—
Proceeds from bank borrowings		17,753	—	—
Repayment of bank borrowings		(26,923)		_
Payment of issuance costs		(83)	(29,509)	(8,134)
Net cash (used in)/generated from financing activities		(82,763)	650,028	296,434
Net (decrease)/increase in cash and cash equivalents		(54,774)	139,485	108,927
Effect of exchange rate changes on cash and cash				
equivalents		(9,490)	2,427	5,546
		(64,264)	141,912	114,473
Cash and cash equivalents				
Cash and cash equivalents at beginning of year		377,542	235,630	121,157
Cash and cash equivalents at end of year		313,278	377,542	235,630
Supplemental disclosure for cash flow information				
Cash paid for interest		150	425	815
Cash paid for tax, net of refunds	24(iii)	18,891	5,014	5,940
Supplemental disclosure for non-cash activities				
Increase in accrued capital expenditures		9,618	8,607	298
Vesting of treasury shares for LTIP	17(ii)	12,034	1,450	4,828



# HUTCHMED (CHINA) LIMITED NOTES TO THE 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 investees have research and development facilities and manufacturing plants in the People's Republic of China (the "PRC") and sell their products mainly in the PRC, 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 ("HKEX") and the AIM market of the London Stock Exchange, and its American depositary shares ("ADS") are traded on the Nasdaq Global Select Market.

# Liquidity

As at December 31, 2022, the Group had accumulated losses of US\$971,481,000 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 December 31, 2022, the Group had cash and cash equivalents of US\$313,278,000, short-term investments of US\$317,718,000 and unutilized bank borrowing facilities of US\$140,289,000. Short-term investments comprised of bank deposits maturing over three months. The Group's operating plan includes the continued receipt of dividends from an equity investee. Dividends received for the years ended December 31, 2022, 2021 and 2020 were US\$43,718,000, US\$49,872,000 and US\$86,708,000 respectively.

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



# 2. Particulars of Principal Subsidiaries and Equity Investee

	Place of establishment and	Equity interest a the Gr Decemb	oup	
Name	operations	2022	2021	Principal activities
Subsidiaries				
HUTCHMED Limited	PRC	99.75 %	99.75 %	Research, development, manufacture and commercialization of pharmaceutical products
HUTCHMED International Corporation	U.S.	99.75 %	99.75 %	Provision of professional, scientific and technical support services
Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited ("HSPL")	PRC	50.87 %	50.87 %	Provision of sales, distribution and marketing services to pharmaceutical manufacturers
Hutchison Healthcare Limited	PRC	100 %	100 %	Manufacture and distribution of healthcare products
Hutchison Hain Organic (Hong Kong) Limited ("HHOHK") (note)	Hong Kong	50 %	50 %	Wholesale and trading of healthcare and consumer products
HUTCHMED Science Nutrition Limited	Hong Kong	100 %	100 %	Wholesale and trading of healthcare and consumer products
Equity investee				
Shanghai Hutchison Pharmaceuticals Limited ("SHPL")	PRC	50 %	50 %	Manufacture and distribution of prescription drug products

Note: HHOHK is regarded as a subsidiary of the Company, as while both its shareholders have equal representation at the board, in the event of a deadlock, the Group has a casting vote and is therefore able to unilaterally control the financial and operating policies of HHOHK.

# 3. Summary of Significant Accounting Policies

# Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements reflect the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. All inter-company balances and transactions have been eliminated in consolidation. The consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the U.S. ("U.S. GAAP").

# Use of Estimates

The preparation of 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 consolidated financial statements and the reported amounts of revenues and expenses during the reporting period.

# Foreign Currency Translation

The Company's presentation currency and functional currency is the U.S. dollar ("US\$"). The financial statements of its subsidiaries with a functional currency other than the US\$ have been translated into the Company's presentation currency. All assets and liabilities of the subsidiaries are translated using year-end exchange rates and revenues and expenses are translated at average exchange rates for the year. Translation adjustments are reflected in accumulated other comprehensive (loss)/income in shareholders' equity.

Net foreign currency exchange losses of US\$5,704,000 and net foreign currency exchange gains of US\$1,671,000 and US\$3,265,000 were recorded in other expense and income in the consolidated statements of operations for the years ended December 31, 2022, 2021 and 2020 respectively.

# Foreign Currency Risk

The Group's operating transactions and its assets and liabilities in the PRC are mainly denominated in Renminbi ("RMB"), which is not freely convertible into foreign currencies. The Group's cash and cash equivalents denominated in RMB are subject to government controls. The value of the RMB is subject to fluctuations from central government policy changes and international economic and political developments that affect the supply and demand of RMB in the foreign exchange market. In the PRC, certain foreign exchange transactions are required by law to be transacted only by authorized financial institutions at exchange rates set by the People's Bank of China (the "PBOC"). Remittances in currencies other than RMB by the Group in the PRC must be processed through the PBOC or other PRC foreign exchange regulatory bodies which require certain supporting documentation in order to complete the remittance.

## Allowance for Current Expected Credit Losses and Concentration of Credit Risk

Financial instruments that potentially expose the Group to credit risk consist primarily of cash and cash equivalents, short-term investments, and financial assets not carried at fair value including accounts receivable and other receivables.

The Group recognizes an allowance for current expected credit losses ("CECLs") on financial assets not carried at fair value. CECLs are calculated over the expected life of the financial assets on an individual or a portfolio basis considering information available about the counterparties' credit situation and collectability of the specific cash flows, including information about past events, current conditions and future forecasts.

The Group places substantially all of its cash and cash equivalents and short-term investments in major financial institutions, which management believes are of high credit quality. The Group has a practice to limit the amount of credit exposure to any particular financial institution. Additionally, the Group has policies in place to ensure that sales are made to customers with an appropriate credit history and the Group performs periodic credit evaluations of its customers. Normally the Group does not require collateral from trade debtors. The Group has not had any material credit losses.

## Cash and Cash Equivalents

The Group considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand and bank deposits and are stated at cost, which approximates fair value.

# Short-term Investments

Short-term investments include deposits placed with banks with original maturities of more than three months but less than one year.

## Accounts Receivable

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. The allowance for CECLs reflects the Group's current estimate of credit losses expected to be incurred over the life of the receivables. The Group considers various factors in establishing, monitoring, and adjusting its allowance for CECLs including the aging of the accounts and aging trends, the historical level of charge-offs, and specific exposures related to particular customers. The Group also monitors other risk factors and forward-looking information, such as country risk, when determining credit limits for customers and establishing adequate allowances for CECLs. Accounts receivable are written off after all reasonable means to collect the full amount (including litigation, where appropriate) have been exhausted.

## Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the weighted average cost method. The cost of finished goods comprises raw materials, direct labor, other direct costs and related production overheads based on normal operating capacity. Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses. A provision for excess and obsolete inventory will be made based primarily on forecasts of product demand and production requirements. The excess balance determined by this analysis becomes the basis for excess inventory charge and the writtendown value of the inventory becomes its cost. Written-down inventory is not written up if market conditions improve.



## Property, Plant and Equipment

Property, plant and equipment consist of buildings, leasehold improvements, plant and equipment, furniture and fixtures, other equipment and motor vehicles. Property, plant and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets.

Buildings	20 years
Plant and equipment	5-10 years
Furniture and fixtures, other equipment	
and motor vehicles	4-5 years
Leasehold improvements	Shorter of (a) 5 years or (b) remaining term of lease

Additions and improvements that extend the useful life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

#### Impairment of Long-Lived Assets

The Group evaluates the recoverability of long-lived assets in accordance with authoritative guidance on accounting for the impairment or disposal of long-lived assets. The Group evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. If indicators of impairment exist, the first step of the impairment test is performed to assess if the carrying value of the net assets exceeds the undiscounted cash flows of the assets. If yes, the second step of the impairment test is performed in order to determine if the carrying value of the net assets exceeds the fair value. If yes, impairment is recognized for the excess.

#### Investments in Equity Investees

Investments in equity investees over which the Group has significant influence are accounted for using the equity method. The Group evaluates equity method investments for impairment when events or circumstances suggest that their carrying amounts may not be recoverable. An impairment charge would be recognized in earnings for a decline in value that is determined to be other-than-temporary after assessing the severity and duration of the impairment and the likelihood of recovery before disposal. The investments are recorded at fair value only if impairment is recognized.

## Leasehold Land

Leasehold land represents fees paid to acquire the right to use the land on which various plants and buildings are situated for a specified period of time from the date the respective right was granted and are stated at cost less accumulated amortization and impairment loss, if any. Amortization is computed using the straight-line basis over the lease period of 50 years.

## Goodwill

Goodwill represents the excess of the purchase price plus fair value of non-controlling interests over the fair value of identifiable assets and liabilities acquired. Goodwill is not amortized, but is tested for impairment at the reporting unit level on at least an annual basis or when an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. When performing an evaluation of goodwill impairment, the Group has the option to first assess qualitative factors, such as significant events and changes to expectations and activities that may have occurred since the last impairment evaluation, to determine if it is more likely than not that goodwill might be impaired. If as a result of the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the quantitative fair value test is performed to determine if the fair value of the reporting unit exceeds its carrying value.

## **Other Intangible Assets**

Other intangible assets with finite useful lives are carried at cost less accumulated amortization and impairment loss, if any. Amortization is computed using the straight-line basis over the estimated useful lives of the assets.



#### **Borrowings**

Borrowings are recognized initially at fair value, net of debt issuance costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of debt issuance costs) and the redemption value is recognized in the consolidated statements of operations over the period of the borrowings using the effective interest method.

#### **Ordinary Shares**

The Company's ordinary shares are stated at par value of US\$0.10 per ordinary share. The difference between the consideration received, net of issuance cost, and the par value is recorded in additional paid-in capital.

#### **Treasury Shares**

The Group accounts for treasury shares under the cost method. The treasury shares are purchased for the purpose of the LTIP and held by a trustee appointed by the Group (the "Trustee") prior to vesting.

#### Share-Based Compensation

#### Share options

The Group recognizes share-based compensation expense on share options granted to employees and directors based on their estimated grant date fair value using the Polynomial model. This Polynomial pricing model uses various inputs to measure fair value, including the market value of the Company's underlying ordinary shares at the grant date, contractual terms, estimated volatility, risk-free interest rates and expected dividend yields. The Group recognizes share-based compensation expense in the consolidated statements of operations on a graded vesting basis over the requisite service period, and accounts for forfeitures as they occur.

Share options are classified as equity-settled awards. Share-based compensation expense, when recognized, is charged to the consolidated statements of operations with the corresponding entry to additional paid-in capital.

#### LTIP

The Group recognizes the share-based compensation expense on the LTIP awards based on a fixed or determinable monetary amount on a straight-line basis for each annual tranche awarded over the requisite period. For LTIP awards with performance targets, prior to their determination date, the amount of LTIP awards that is expected to vest takes into consideration the achievement of the performance conditions and the extent to which the performance conditions are likely to be met. Performance conditions vary by awards, and may include targets for shareholder returns, financings, revenues, net profit after taxes and the achievement of clinical and regulatory milestones.

These LTIP awards are classified as liability-settled awards before the determination date (i.e. the date when the achievement of any performance conditions are known), 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. As the extent of achievement of the performance targets is uncertain prior to the determination date, a probability based on management's assessment of the achievement of the performance targets has been assigned to calculate the amount to be recognized as an expense over the requisite period.

After the determination date or if the LTIP awards have no performance conditions, the LTIP awards are classified as equity-settled awards. If the performance target is achieved, the Group will pay the determined monetary amount to the Trustee to purchase ordinary shares of the Company or the equivalent ADS. Any cumulative compensation expense previously recognized as a liability will be transferred to additional paid-in capital. If the performance target is not achieved, no ordinary shares or ADS of the Company will be purchased and the amount previously recorded in the liability will be reversed and included in the consolidated statements of operations.

#### **Defined Contribution Plans**

The Group's subsidiaries in the PRC participate in a government-mandated multi-employer defined contribution plan pursuant to which certain retirement, medical and other welfare benefits are provided to employees. The relevant labor regulations require the Group's subsidiaries in the PRC to pay the local labor and social welfare authority's monthly contributions at a stated contribution rate based on the monthly basic



compensation of qualified employees. The relevant local labor and social welfare authorities are responsible for meeting all retirement benefits obligations and the Group's subsidiaries in the PRC have no further commitments beyond their monthly contributions. The contributions to the plan are expensed as incurred.

The Group also makes payments to other defined contribution plans for the benefit of employees employed by subsidiaries outside the PRC. The defined contribution plans are generally funded by the relevant companies and by payments from employees.

The Group's contributions to defined contribution plans for the years ended December 31, 2022, 2021 and 2020 amounted to US\$11,795,000, US\$7,181,000 and US\$2,660,000 respectively.

#### **Revenue Recognition**

Revenue is measured based on consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Group from a customer, are also excluded from revenue. The Group recognizes revenue when it satisfies a performance obligation by transferring control over a good, service or license to a customer.

## (i) Goods and services

The Group principally generates revenue from (1) sales of goods, which are the manufacture or purchase and distribution of pharmaceutical products and other consumer health products, and (2) provision of services, which are the provision of sales, distribution and marketing services to pharmaceutical manufacturers. The Group evaluates whether it is the principal or agent for these contracts. Where the Group obtains control of the goods for distribution, it is the principal (i.e. recognizes sales of goods on a gross basis). Where the Group does not obtain control of the goods for distribution, it is the agent (i.e. recognizes provision of services on a net basis). Control is primarily evidenced by taking physical possession and inventory risk of the goods.

Revenue from sales of goods is recognized when the customer takes possession of the goods. This usually occurs upon completed delivery of the goods to the customer site. The amount of revenue recognized is adjusted for expected sales incentives as stipulated in the contract, which are generally issued to customers as direct discounts at the point-of-sale or indirectly in the form of rebates. Sales incentives are estimated using the expected value method. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns.

Revenue from provision of services is recognized when the benefits of the services transfer to the customer over time, which is based on the proportionate value of services rendered as determined under the terms of the relevant contract. Additionally, when the amounts that can be invoiced correspond directly with the value to the customer for performance completed to date, the Group recognizes revenue from provision of services based on amounts that can be invoiced to the customer.

Deferred revenue is recognized if consideration is received in advance of transferring control of the goods or rendering of services. Accounts receivable is recognized if the Group has an unconditional right to bill the customer, which is generally when the customer takes possession of the goods or services are rendered. Payment terms differ by subsidiary and customer, but generally range from 45 to 180 days from the invoice date.

#### (ii) License and collaboration contracts

The Group's Oncology/Immunology reportable segment includes revenue generated from license and collaboration contracts, which generally contain multiple performance obligations including (1) the license to the commercialization rights of a drug compound and (2) the research and development services for each specified treatment indication, which are accounted for separately if they are distinct, i.e. if a product or service is separately identifiable from other items in the arrangement and if a customer can benefit from it on its own or with other resources that are readily available to the customer.

The transaction price generally includes fixed and variable consideration in the form of upfront payment, research and development cost reimbursements, contingent milestone payments and sales-based royalties. Contingent milestone payments are not included in the transaction price until it becomes probable that a significant reversal of revenue will not occur, which is generally when the specified milestone is achieved. The allocation of the transaction price to each performance obligation is based on the relative standalone selling prices of each performance obligation determined at the inception of the contract. The Group estimates the standalone selling prices based on the income approach. Control of the license to the drug compounds transfers at the inception date of the collaboration agreements and consequently, amounts allocated to this performance obligation are generally recognized at a point in time. Conversely, research and development services for each



specified indication are performed over time and amounts allocated to these performance obligations are generally recognized over time using cost inputs as a measure of progress. The Group has determined that research and development expenses provide an appropriate depiction of measure of progress for the research and development services. Changes to estimated cost inputs may result in a cumulative catch-up adjustment. Royalty revenues are recognized as future sales occur as they meet the requirements for the sales-usage based royalty exception.

Deferred revenue is recognized if allocated consideration is received in advance of the Group rendering research and development services or earning royalties on future sales. Accounts receivable is recognized based on the terms of the contract and when the Group has an unconditional right to bill the customer, which is generally when research and development services are rendered.

#### **Research and Development Expenses**

Research and development expenses include the following: (i) research and development costs, which are expensed as incurred; (ii) acquired in-process research and development ("IPR&D") expenses, which include the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use; and (iii) milestone payment obligations for externally developed IPR&D projects approval of the product in the in-licensed territory, which are accrued when the event requiring payment of the milestone occurs (milestone payment obligations incurred upon regulatory approval are recorded as other intangible assets).

#### **Collaborative Arrangements**

The Group enters into collaborative arrangements with collaboration partners that fall under the scope of Accounting Standards Codification ("ASC") 808, Collaborative Arrangements ("ASC 808"). The Group records all expenditures for such collaborative arrangements in research and development expenses as incurred, including payments to third party vendors and reimbursements to collaboration partners, if any. Reimbursements from collaboration partners are recorded as reductions to research and development expenses and development expenses and accrued when they can be contractually claimed.

#### **Government Grants**

Grants from governments are recognized at their fair values. Government grants that are received in advance are deferred and recognized in the consolidated statements of operations over the period necessary to match them with the costs that they are intended to compensate. Government grants in relation to the achievement of stages of research and development projects are recognized in the consolidated statements of operations when amounts have been received and all attached conditions have been met. Non-refundable grants received without any further obligations or conditions attached are recognized immediately in the consolidated statements of operations.

## Leases

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

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

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



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

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

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

#### Income Taxes

The Group accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the income tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some of the net deferred income tax asset will not be realized.

The Group accounts for an uncertain tax position in the consolidated financial statements only if it is more likely than not that the position is sustainable based on its technical merits and consideration of the relevant tax authority's widely understood administrative practices and precedents. If the recognition threshold is met, the Group records the largest amount of tax benefit that is greater than 50 percent likely to be realized upon ultimate settlement.

The Group recognizes interest and penalties for income taxes, if any, under income tax payable on its consolidated balance sheets and under other expenses in its consolidated statements of operations.

#### Losses per Share

Basic losses per share is computed by dividing net loss attributable to the Company by the weighted average number of outstanding ordinary shares in issue during the year. Weighted average number of outstanding ordinary shares in issue excludes treasury shares.

Diluted losses per share is computed by dividing net loss attributable to the Company by the weighted average number of outstanding ordinary shares in issue and dilutive ordinary share equivalents outstanding during the year. Dilutive ordinary share equivalents include ordinary shares and treasury shares issuable upon the exercise or settlement of share-based awards or warrants issued by the Company using the treasury stock method. The computation of diluted losses per share does not assume conversion, exercise, or contingent issuance of securities that would have an anti-dilutive effect.

#### Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief executive officer who is the Group's chief operating decision maker. The chief operating decision maker reviews the Group's internal reporting in order to assess performance and allocate resources.

#### Profit Appropriation and Statutory Reserves

The Group's subsidiaries and equity investees established in the PRC are required to make appropriations to certain non-distributable reserve funds.

In accordance with the relevant laws and regulations established in the PRC, the Company's subsidiaries registered as wholly-owned foreign enterprise have to make appropriations from their after-tax profits (as determined under generally accepted accounting principles in the PRC ("PRC GAAP") to reserve funds including general reserve fund, enterprise expansion fund and staff bonus and welfare fund. The appropriation to the general reserve fund must be at least 10% of the after-tax profits calculated in accordance with PRC GAAP. Appropriation is not required if the general reserve fund has reached 50% of the registered capital of the company. Appropriations to the enterprise expansion fund and staff bonus and welfare fund are made at the



respective company's discretion. For the Group's equity investees, the amount of appropriations to these funds are made at the discretion of their respective boards.

In addition, Chinese domestic companies must make appropriations from their after-tax profits as determined under PRC GAAP to non-distributable reserve funds including statutory surplus fund and discretionary surplus fund. The appropriation to the statutory surplus fund must be 10% of the after-tax profits as determined under PRC GAAP. Appropriation is not required if the statutory surplus fund has reached 50% of the registered capital of the company. Appropriation to the discretionary surplus fund is made at the respective company's discretion.

The use of the general reserve fund, enterprise expansion fund, statutory surplus fund and discretionary surplus fund is restricted to the offsetting of losses or increases to the registered capital of the respective company. The staff bonus and welfare fund is a liability in nature and is restricted to fund payments of special bonus to employees and for the collective welfare of employees. All these reserves are not permitted to be transferred to the company as cash dividends, loans or advances, nor can they be distributed except under liquidation.

# 4. Fair Value Disclosures

The following table presents the Group's financial instruments by level within the fair value hierarchy under ASC 820, Fair Value Measurement:

		Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total	
		(in US	\$'000)		
As at December 31, 2021					
Warrant (Note 19)		2,452		2,452	

Cash equivalents, short-term investments, accounts receivable, other receivables, accounts payable and other payables are carried at cost, which approximates fair value due to the short-term nature of these financial instruments, and are therefore excluded from the above table. Bank borrowings are floating rate instruments and carried at amortized cost, which approximates fair values, and are therefore excluded from the above table.

# 5. Cash and Cash Equivalents and Short-term Investments

	December 31,		
	2022	2021	
	(in US\$'000)		
Cash and Cash Equivalents			
Cash at bank and on hand	178,326	104,620	
Bank deposits maturing in three months or less	134,952	272,922	
	313,278	377,542	
Short-term Investments			
Bank deposits maturing over three months (note)	317,718	634,158	
	630,996	1,011,700	

Note: The maturities for short-term investments ranged from 91 to 99 days and 91 to 180 days for the years ended December 31, 2022 and 2021 respectively.



Certain cash and bank balances denominated in RMB, 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:

	December	December 31,		
	2022	2021		
	(in US\$'00	0)		
US\$	533,173	895,935		
RMB	79,319	53,455		
Hong Kong dollar ("HK\$")	16,721	60,535		
£	1,370	1,090		
Euro	413	685		
	630,996	1,011,700		

# 6. Accounts Receivable

Accounts receivable from contracts with customers consisted of the following:

	December	December 31,		
	2022	2021		
	(in US\$'00	00)		
Accounts receivable-third parties	94,531	82,434		
Accounts receivable—related parties (Note 23(ii))	3,517	1,166		
Allowance for credit losses	(60)	(20)		
Accounts receivable, net	97,988	83,580		

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:

	December	December 31,		
	2022	2021		
	(in US\$'00	)0)		
Not later than 3 months	84,007	78,288		
Between 3 months to 6 months	7,478	2,867		
Between 6 months to 1 year	1,947	78		
Later than 1 year	1,099	1,201		
Accounts receivable—third parties	94,531	82,434		

Movements on the allowance for credit losses:

	2022	2021	2020
		(in US\$'000)	
As at January 1	20	95	16
Increase in allowance for credit losses	150	16	95
Decrease in allowance due to subsequent collection	(107)	(92)	(18)
Exchange difference	(3)	1	2
As at December 31	60	20	95



# 7. Other receivables, prepayments and deposits

Other receivables, prepayments and deposits consisted of the following:

	December 3	December 31,		
	2022	2021		
	(in US\$'000	)		
Dividend receivables (Note 22)	26,246	46,387		
Prepayments	22,329	14,128		
Value-added tax receivables	1,491	16,616		
Deposits	1,214	1,255		
Amounts due from related parties (Note 23(ii))	998	1,149		
Others	1,936	1,506		
	54,214	81,041		

No allowance for credit losses has been made for other receivables, prepayments and deposits for the years ended December 31, 2022 and 2021.

# 8. Inventories

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

	Decembe	December 31,		
	2022	2021		
	(in US\$'	000)		
Raw materials	27,392	15,837		
Finished goods	29,298	19,918		
	56,690	35,755		

# 9. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

		Leasehold	Plant and	Furniture and fixtures, other equipment and motor	Construction	
	Buildings	improvements	equipment	vehicles S\$'000)	in progress	Total
Cost			(iii U	5\$ 000)		
As at January 1, 2022	2,432	17,828	5,987	27,957	19,970	74,174
Additions		171	541	4,945	40,625	46,282
Disposals	_	(1,105)	(2)	(529)		(1,636)
Transfers	_	1,336	1,412	1,637	(4,385)	
Exchange differences	(199)	(1,394)	(484)	(2,272)	(1,660)	(6,009)
As at December 31,						
2022	2,233	16,836	7,454	31,738	54,550	112,811
Accumulated				,		,
depreciation						
As at January 1, 2022	1,788	11,571	2,352	17,188	—	32,899
Depreciation	116	3,741	590	3,880	_	8,327
Disposals	_	(1,018)	(2)	(505)	_	(1,525)
Transfers	_		(56)	56	_	_
Exchange differences	(151)	(1,012)	(214)	(1,460)	_	(2,837)
As at December 31,			i	i		· · · · · ·
2022	1,753	13,282	2,670	19,159		36,864
Net book value	· · · · · · · · · · · · · · · · · · ·				· · · · · · · · · · · · · · · · · · ·	
As at December 31,						
2022	480	3,554	4,784	12,579	54,550	75,947
				Furniture and fixtures, other equipment		
	Buildings	Leasehold improvements	Plant and equipment	and motor vehicles	Construction	Total
	Buitaings	improvements		\$\$'000)	in progress	TOTAL
Cost			(	,		
As at January 1, 2021	2,372	16,346	5,643	23,040	3,050	50,451
Additions	_	452	24	3,189	19,669	23,334
Disposals		(275)	(19)	(705)		(999)
Transfers		916	197	1,849	(2,962)	
Exchange differences	60	389	142	584	213	1,388
As at December 31,						
2021	2,432	17,828	5,987	27,957	19,970	74,174
Accumulated depreciation						
As at January 1, 2021	1,626	8,652	1,747	14,256		26,281
Depreciation	120	2,904	574	3,244		6,842
Disposals		(223)	(18)	(688)	—	(929)
Exchange differences	42	238	49	376		705
As at December 31,						
2021	1,788	11,571	2,352	17,188		32,899
Net book value						
As at December 31,						
2021	644	6,257	3,635	10,769	19,970	41,275



# 10. Leases

Leases consisted of the following:

	December 31,		
	2022	2021	
	(in US\$'00	00)	
Right-of-use assets			
Offices	6,634	10,605	
Factories	387	702	
Warehouses (note)	1,500	281	
Others	201	291	
Total right-of-use assets	8,722	11,879	
Lease liabilities—current	3,708	4,917	
Lease liabilities—non-current	5,196	7,161	
Total lease liabilities	8,904	12,078	

Note: Includes US\$1.5 million right-of-use asset for warehouses in Suzhou that is leased through June 2026 in which the contract has a termination option with 3-month advance notice. The termination option was not recognized as part of the right-of-use asset and lease liability as it is uncertain that the Group will exercise such option.

Lease activities are summarized as follows:

	Year Ended December 31,		
	2022	2021	
	(in US\$'	000)	
Lease expenses:			
Short-term leases with lease terms equal or less than 12 months	134	106	
Leases with lease terms greater than 12 months	5,238	4,306	
	5,372	4,412	
Cash paid on lease liabilities	5,212	4,954	
Non-cash: Lease liabilities recognized from obtaining right-of-use			
assets	2,689	7,665	
Non-cash: Lease liabilities changed in relation to modifications and			
terminations	(499)	(33)	

Lease contracts are typically within a period of 1 to 8 years. The weighted average remaining lease term and the weighted average discount rate as at December 31, 2022 was 3.24 years and 3.04% respectively. The weighted average remaining lease term and the weighted average discount rate as at December 31, 2021 was 3.38 years and 3.33% respectively.

Future lease payments are as follows:

	December 31, 2022
	(in US\$'000)
Lease payments:	
Not later than 1 year	3,908
Between 1 to 2 years	2,471
Between 2 to 3 years	1,177
Between 3 to 4 years	911
Between 4 to 5 years	680
Later than 5 years	115
Total lease payments	9,262
Less: Discount factor	(358)
Total lease liabilities	8,904



# **11. Investments in Equity Investees**

Investments in equity investees consisted of the following:

	December	December 31,	
	2022	2021	
	(in US\$'00	)0)	
SHPL	73,461	75,999	
Other	316	480	
	73,777	76,479	

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

Summarized financial information for the significant equity investees SHPL and HBYS (sold in 2021), is as follows:

## (i) Summarized balance sheets

	SHPL	SHPL December 31,		
	December			
	2022	2021		
	(in US\$'00	0)		
Current assets	214,267	190,260		
Non-current assets	80,062	91,605		
Current liabilities	(147,952)	(128,993)		
Non-current liabilities	(4,944)	(7,131)		
Net assets	141,433	145,741		

# (ii) Summarized statements of operations

	SHPL			HBYS <sup>(note (a))</sup>	
	Year Ended December 31,				
	2022	2021	2020	2021 <sup>(note (b))</sup>	2020
			(in US\$'000)		
Revenue	370,600	332,648	276,354	209,528	232,368
Gross profit	281,113	255,089	204,191	111,066	116,804
Interest income	980	1,216	975	205	271
Finance cost					(5)
Profit before taxation	116,454	105,325	77,837	36,715	107,715
Income tax expense (note (c))	(16,738)	(15,896)	(10,833)	(4,840)	(16,494)
Net income (note(d))	99,716	89,429	67,004	31,875	91,221
Non-controlling interests	—		—	(36)	62
Net income attributable to the					
shareholders of equity investee	99,716	89,429	67,004	31,839	91,283

Notes:

- (a) In 2020, HBYS entered into an agreement with the government to return the land use right for a plot of land in Guangzhou to the government and recognized land compensation of RMB569.2 million (approximately US\$86.1 million). In June 2021, HBYS received a completion confirmation from the government and became entitled to a land compensation bonus of RMB110.3 million (approximately US\$17.0 million) and recorded a gain before tax of RMB106.8 million (approximately US\$16.4 million) after deducting costs of RMB3.5 million (approximately US\$0.6 million).
- (b) The summarized statement of operations for HBYS for the year ended December 31, 2021 includes the period when HBYS was the Group's equity investee from January 1, 2021 to September 28, 2021, the completion date of the divestment. The Group has accounted for the investment in HBYS under the equity method up to September 28, 2021.

- (c) The main entity within the SHPL group has been granted the High and New Technology Enterprise ("HNTE") status. Accordingly, the entity was eligible to use a preferential income tax rate of 15% for the years ended December 31, 2022, 2021 and 2020.
- (d) Net income is before elimination of unrealized profits on transactions with the Group. The amounts eliminated were approximately US\$110,000, US\$36,000 and nil for the years ended December 31, 2022, 2021 and 2020 respectively.

For the years ended December 31, 2022, 2021 and 2020, other equity investee had net income of approximately US\$10,000 and US\$41,000 and net losses of approximately US\$194,000 respectively. In August 2022, the Group entered into an agreement with a third party (the "Buyer") to sell its entire investment in other equity investee for cash consideration of RMB2.2 million (approximately US\$324,000) with closing subject to regulatory approval in the PRC.

# (iii) Reconciliation of summarized financial information

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

	SHPL		НВҮ	′S	
	2022	2021	2020	2021	2020
			(in US\$'000)		
Opening net assets after non-controlling					
interests as at January 1	145,741	152,714	146,759	119,424	44,541
Net income attributable to the shareholders					
of equity investee	99,716	89,429	67,004	31,839	91,283
Purchase of additional interests in a					
subsidiary of an equity investee (note)	—	_	_	_	(347)
Dividends declared	(87,436)	(99,744)	(72,179)	(106,159)	(20,756)
Other comprehensive (loss)/income	(16,588)	3,342	11,130	1,387	4,703
Closing net assets after non-controlling					
interests as at December 31	141,433	145,741	152,714	46,491	119,424
Group's share of net assets	70,717	72,871	76,357	23,246	59,712
Goodwill	2,872	3,128	3,051	—	_
Elimination of unrealized profits on					
downstream sales	(128)	_	—	—	—
Divestment (Note 22)	_	_	_	(23,246)	_
Carrying amount of investments as at					
December 31	73,461	75,999	79,408		59,712

Note: During the year ended December 31, 2020, HBYS acquired an additional 30% interest in a subsidiary and after the acquisition, it became a wholly owned subsidiary of HBYS.

SHPL had the following capital commitments:

	December 31, 2022
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	1,307



# 12. Accounts Payable

	Decembe	December 31,		
	2022	2021		
	(in US\$'000)			
Accounts payable—third parties	68,193	39,115		
Accounts payable—non-controlling shareholders of				
subsidiaries (Note 23(iv))	2,922	2,062		
	71,115	41,177		

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

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

	December	December 31,		
	2022	2021		
	(in US\$'00	0)		
Not later than 3 months	60,553	35,615		
Between 3 months to 6 months	7,216	3,705		
Between 6 months to 1 year	2,137	588		
Later than 1 year	1,209	1,269		
	71,115	41,177		

# 13. Other Payables, Accruals and Advance Receipts

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

	December 31,		
	2022	2021	
	(in US\$'000	))	
Accrued research and development expenses	156,134	116,134	
Accrued salaries and benefits	42,442	41,786	
Accrued capital expenditures	21,390	11,343	
Accrued administrative and other general expenses	14,491	15,836	
Accrued selling and marketing expenses	11,564	8,412	
Deposits	3,616	2,111	
Amounts due to related parties (Note 23(ii))	2,101	1,915	
Deferred government grants	673	314	
Others	12,210	12,988	
	264,621	210,839	

# 14. Bank Borrowings

Bank borrowings consisted of the following:

	Decemb	December 31,	
	2022	2021	
	(in US\$	'000)	
	—	26,905	
urrent	18,104	—	

The weighted average interest rate for outstanding bank borrowings for the years ended December 31, 2022 and 2021 was 1.73% per annum and 1.08% per annum respectively. The carrying amounts of the Group's outstanding bank borrowings as at December 31, 2022 and 2021 were denominated in RMB and HK\$ respectively.



# (i) 3-year term loan and revolving loan facilities and 1-year revolving loan facility

In May 2019, the Group through its subsidiary, entered into a facility agreement with a bank for the provision of unsecured credit facilities in the aggregate amount of HK\$400,000,000 (US\$51,282,000). The 3-year credit facilities included (i) a HK\$210,000,000 (US\$26,923,000) term loan facility and (ii) a HK\$190,000,000 (US\$24,359,000) revolving loan facility, both with an interest rate at the Hong Kong Interbank Offered Rate ("HIBOR") plus 0.85% per annum, and an upfront fee of HK\$819,000 (US\$105,000) on the term loan. These credit facilities were guaranteed by the Company. The term loan was drawn in October 2019 and was repaid in May 2022. The revolving loan facility also expired in May 2022.

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 HIBOR plus 0.5% per annum. This credit facility is guaranteed by the Company. As at December 31, 2022, no amount was drawn from the revolving loan facility.

## (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\$108,393,000) 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 December 31, 2022 and 2021, RMB126,083,000 (US\$18,104,000) and nil were utilized from the fixed asset loan facility respectively, of which RMB769,000 (US\$110,000) and nil were related to capitalized interest respectively.

## (iii) 2-year revolving loan facility

In August 2020, the Group through its subsidiary, entered into a 2-year revolving loan facility with a bank in the amount of HK\$117,000,000 (US\$15,000,000) with an interest rate at HIBOR plus 4.5% per annum. This credit facility was guaranteed by the Company. The revolving loan facility expired in August 2022.

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

	December 31,		
	2022	2021	
	(in US\$'000)		
Not later than 1 year	—	26,923	
Between 1 to 3 years	360	—	
Between 3 to 4 years	839	—	
Between 4 to 5 years	1,079	—	
Later than 5 years	15,826	—	
	18,104	26,923	

As at December 31, 2022 and 2021, the Group had unutilized bank borrowing facilities of US\$140,289,000 and US\$157,430,000 respectively.

# **15. Commitments and Contingencies**

The Group had the following capital commitments:

	December 31, 2022
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	22,130

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



# 16. Ordinary Shares

As at December 31, 2022, the Company is authorized to issue 1,500,000,000 ordinary shares.

On April 14, 2021, the Company issued 16,393,445 ordinary shares to a third party for gross proceeds of US\$100.0 million through a PIPE. Issuance costs totaled US\$0.1 million.

On June 30, 2021 and July 15, 2021, the Company issued an aggregate of 119,600,000 ordinary shares in a public offering on the HKEX with over-allotment option exercised in full for aggregate gross proceeds of US\$614.9 million. Issuance costs totaled US\$29.7 million.

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

# 17. 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 December 31, 2022, the aggregate number of shares issuable under the Hutchmed Share Option Scheme was 48,611,458 ordinary shares and the aggregate number of shares issuable under the prior share option scheme which expired in 2016 was 660,570 ordinary shares. The Company will issue new shares to satisfy share option exercises. Additionally, the number of shares authorized but unissued was 635,224,660 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, 2020	19,432,560	4.48	6.67	24,316
Granted	15,437,080	4.66		
Exercised	(480,780)	1.23		
Cancelled	(4,486,200)	5.02		
Expired	(741,670)	6.46		
Outstanding at December 31, 2020	29,160,990	4.49	7.21	53,990
Granted	10,174,840	5.96		
Exercised	(815,190)	3.01		
Cancelled	(1,287,650)	5.50		
Expired	(42,400)	5.52		
Outstanding at December 31, 2021	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
Vested and exercisable at December 31, 2021	16,077,770	4.24	4.91	46,491
Vested and exercisable at December 31, 2022	21,113,285	4.57	4.80	6,288

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.

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

	Year Ended December 31,		
	2022	2021	2020
Weighted average grant date fair value of share options (in US\$ per share)	0.85	2.24	1.76
Significant inputs into the valuation model (weighted average):			
Exercise price (in US\$ per share)	2.26	5.96	4.66
Share price at effective date of grant (in US\$ per share)	2.22	5.91	4.66
Expected volatility (note (a))	46.7%	41.1%	42.6%
Risk-free interest rate (note (b))	2.98%	1.62%	0.59%
Contractual life of share options (in years)	10	10	10
Expected dividend yield (note (c))	0%	0%	0%

Notes:

- (a) The Company calculated its expected volatility with reference to the historical volatility prior to the issuances of share options.
- (b) For share options exercisable into ADS, 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\$. For share options exercisable into ordinary shares, the risk-free interest rates reference the sovereign yield of the United Kingdom because the Company's ordinary shares are currently listed on AIM and denominated in £.

(c) The Company has not declared or paid any dividends and does not currently expect to do so 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:

	Year Ended December 31,		
	2022	2020	
		(in US\$'000)	
Cash received from share option exercises	174	2,452	593
Total intrinsic value of share option exercises	92	2,999	2,475

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 consolidated statements of operations:

	Yea	Year Ended December 31,		
	2022	2021	2020	
	(in US\$'000)			
Research and development expenses	4,803	8,460	4,061	
Selling and administrative expenses	1,803	7,783	4,586	
Cost of revenues	130	122	90	
	6,736	16,365	8,737	

As at December 31, 2022, the total unrecognized compensation cost was US\$10,907,000, and will be recognized on a graded vesting approach over the weighted average remaining service period of 2.63 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 profit after taxes and the achievement of clinical and regulatory milestones. As the extent of achievement of the performance targets is uncertain prior to the determination date, a probability based on management's assessment on the achievement of the performance target has been assigned to calculate the amount to be recognized as an expense over the requisite period with a corresponding entry to liability.

## LTIP awards after the determination date

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



Granted awards under the LTIP are as follows:

Grant date	Maximum cash amount (in US\$ millions)	Covered financial years	Performance target determination date
April 20, 2020	5.3	2019	note (a)
April 20, 2020	37.4	2020	note (b)
April 20, 2020	1.9	note (c)	note (c)
April 20, 2020	0.2	note (d)	note (d)
August 12, 2020	2.1	2020	note (b)
August 12, 2020	0.3	note (c)	note (c)
March 26, 2021	57.3	2021	note (b)
September 1, 2021	7.3	2021	note (b)
September 1, 2021	0.5	note (c)	note (c)
October 20, 2021	1.7	note (c)	note (c)
December 14, 2021	0.1	note (c)	note (c)
December 14, 2021	0.1	note (d)	note (d)
May 23, 2022	60.4	2022	note (b)
September 13, 2022	3.8	2022	note (b)
September 13, 2022	1.7	note (c)	note (c)

Notes:

- (a) This award does not stipulate performance targets 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) 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.
- (c) 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.
- (d) This award does not stipulate performance targets and will be vested on the first anniversary 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 the form of ordinary shares or ADS of the Company) held by the Trustee were as follows:

	Number of treasury shares	Cost (in US\$'000)
As at January 1, 2020	941,310	6,079
Purchased	3,281,920	12,904
Vested	(712,555)	(4,828)
As at December 31, 2020	3,510,675	14,155
Purchased	4,907,045	27,309
Vested	(278,545)	(1,450)
As at December 31, 2021	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

Based on the estimated achievement of performance conditions for 2022 financial year LTIP awards, the determined monetary amount was US\$17,429,000 which is recognized to share-based compensation expense over the requisite vesting period to March 2025.

For the years ended December 31, 2022, 2021 and 2020, US\$19,031,000, US\$6,618,000 and US\$7,038,000 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:

	Year Ended December 31,		
	2022	2021	2020
		(in US\$'000)	
Research and development expenses	16,101	16,880	7,252
Selling and administrative expenses	7,376	8,451	3,552
Cost of revenues	373	294	101
	23,850	25,625	10,905
Recorded with a corresponding credit to:			
Liability	6,216	14,263	7,778
Additional paid-in capital	17,634	11,362	3,127
	23,850	25,625	10,905

For the years ended December 31, 2022, 2021 and 2020, US\$15,351,000, US\$8,516,000 and US\$4,092,000 were reclassified from liability to additional paid-in capital respectively upon LTIP awards reaching the determination date. As at December 31, 2022 and 2021, US\$3,701,000 and US\$12,836,000 were recorded as liabilities respectively for LTIP awards prior to the determination date.

As at December 31, 2022, the total unrecognized compensation cost was approximately US\$34,668,000, which considers expected performance targets and the amounts expected to vest, and will be recognized over the requisite periods.

# 18. Revenues

The following table presents disaggregated revenue, with sales of goods recognized at a point-in-time and provision of services recognized over time:

	Year Ended December 31, 2022		
	Oncology/Immunology	Other Ventures (in US\$'000)	Total
Goods—Marketed Products	57,057	_	57,057
Goods—Distribution	—	262,565	262,565
Services—Commercialization—Marketed	41,275	_	41,275
Products			
Collaboration Research and			
Development	23,741	—	23,741
-Research and Development	507	_	507
Royalties	26,310	_	26,310
Licensing	14,954	—	14,954
	163,844	262,565	426,409
Third parties	163,337	257,272	420,609
Related parties (Note 23(i))	507	5,293	5,800
	163,844	262,565	426,409

	Year Ended December 31, 2021		
	Oncology/Immunology	Other Ventures	Total
		(in US\$'000)	
Goods—Marketed Products	33,937	—	33,937
Goods—Distribution	—	236,518	236,518
Services—Commercialization—Marketed	27,428	—	27,428
Products			
—Collaboration Research and		—	
Development	18,995		18,995
-Research and Development	525	—	525
Royalties	15,064	—	15,064
Licensing	23,661	—	23,661
	119,610	236,518	356,128
Third parties	119,085	232,262	351,347
Related parties (Note 23(i))	525	4,256	4,781
	119,610	236,518	356,128

	Year Ended December 31, 2020		
	Oncology/Immunology	Other Ventures	Total
		(in US\$'000)	
Goods—Marketed Products	11,329	—	11,329
Goods—Distribution	—	197,761	197,761
Services—Commercialization—Marketed	3,734	_	3,734
Products			
—Collaboration Research and			
Development	9,771	—	9,771
-Research and Development	491		491
Royalties	4,890	—	4,890
	30,215	197,761	227,976
Third parties	29,724	192,277	222,001
Related parties (Note 23(i))	491	5,484	5,975
	30,215	197,761	227,976



The following table presents liability balances from contracts with customers:

	Decembe	er 31,
	2022	2021
	(in US\$'	000)
Deferred revenue		
Current—Oncology/Immunology segment (note (a))	11,817	11,078
Current—Other Ventures segment (note (b))	1,530	1,196
	13,347	12,274
Non-current—Oncology/Immunology segment (note (a))	190	878
Total deferred revenue (note (c) and (d))	13,537	13,152

Notes:

- (a) Oncology/Immunology segment deferred revenue relates to invoiced amounts for royalties where the customer has not yet completed the in-market sale, unamortized upfront and milestone payments 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:

	December 31,	
	2022	2021
	(in US	\$'000)
Not later than 1 year	13,347	12,274
Between 1 to 2 years	150	476
Between 2 to 3 years	40	255
Between 3 to 4 years	—	147
	13,537	13,152

(d) As at January 1, 2022, deferred revenue was US\$13.2 million, of which US\$11.8 million was recognized during the year ended December 31, 2022.

## License and collaboration agreement with Eli Lilly

On October 8, 2013, the Group entered into a licensing, co-development and commercialization agreement in China with Eli Lilly and Company ("Lilly") relating to Elunate ("Lilly Agreement"), also known as fruquintinib, a targeted oncology therapy for the treatment of various types of solid tumors. Under the terms of the Lilly Agreement, the Group is entitled to receive a series of payments up to US\$86.5 million, including upfront payments and development and regulatory approval milestones. Development costs after the first development milestone are shared between the Group and Lilly. Elunate was successfully commercialized in China in November 2018, and the Group receives tiered royalties in the range of 15% to 20% on all sales in China.

In December 2018, the Group entered into various amendments to the Lilly Agreement (the "2018 Amendment"). Under the terms of the 2018 Amendment, the Group is entitled to determine and conduct future life cycle indications ("LCI") development of Elunate in China beyond the three initial indications specified in the Lilly Agreement and will be responsible for all associated development costs. In return, the Group will receive additional regulatory approval milestones of US\$20 million for each LCI approved, for up to three LCI or US\$60 million in aggregate, and will increase tiered royalties to a range of 15% to 29% on all Elunate sales in China upon the commercial launch of the first LCI. Additionally, through the 2018 Amendment, Lilly has provided consent, and freedom to operate, for the Group to enter into joint development collaborations with certain third-party pharmaceutical companies to explore combination treatments of Elunate and various immunotherapy agents. The 2018 Amendment also provided the Group rights to promote Elunate in provinces that represent 30% to 40% of the sales of Elunate in China upon the occurrence of certain commercial milestones by Lilly. Such rights were further amended below.

In July 2020, the Group entered into an amendment to the Lilly Agreement (the "2020 Amendment") relating to the expansion of the Group's role in the commercialization of Elunate across all of China. Under the terms of 65 / 87



the 2020 Amendment, the Group is responsible for providing promotion and marketing services, including the development and execution of all on-the-ground medical detailing, promotion and local and regional marketing activities, in return for service fees on sales of Elunate made by Lilly. In October 2020, the Group commenced such promotion and marketing services. In addition, development and regulatory approval milestones for an initial indication under the Lilly Agreement were increased by US\$10 million in lieu of cost reimbursement.

Upfront and cumulative milestone payments according to the Lilly Agreement received up to December 31, 2022 are summarized as follows:

	(in US\$'000)
Upfront payment	6,500
Development milestone payments achieved	40,000

The Lilly Agreement has the following performance obligations: (1) the license for the commercialization rights to Elunate and (2) the research and development services for the specified indications. The transaction price includes the upfront payment, research and development cost reimbursements, milestone payments and sales-based royalties. Milestone payments were not included in the transaction price until it became probable that a significant reversal of revenue would not occur, which is generally when the specified milestone is achieved. The allocation of the transaction price to each performance obligation was based on the relative standalone selling prices 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 license to Elunate and the research and development services were 90% and 10% respectively. Control of the license to Elunate transferred at the inception date of the agreement and consequently, amounts allocated to this performance obligation were recognized at inception. Conversely, research and development services for each specified indication are performed over time and amounts allocated are recognized over time using the prior and estimated future development costs for Elunate as a measure of progress. Royalties are recognized as future sales occur as they meet the requirements for the sales-usage based royalty exception.

The 2018 Amendment is a separate contract as it added distinct research and development services for the LCIs to the Lilly Agreement. The 2020 Amendment related to the promotion and marketing services is a separate contract as it added distinct services to the Lilly Agreement. Such promotion and marketing services are recognized over time based on amounts that can be invoiced to Lilly. The 2020 Amendment related to the additional development and regulatory approval milestone amounts is a modification as it only affected the transaction price of research and development services for a specific indication under the Lilly Agreement, and therefore, such additional milestone amounts will be included in the transaction price accounted under the Lilly Agreement once the specified milestones are achieved.

Revenue recognized under the Lilly Agreement and subsequent amendments is as follows:

	Year Ended December 31,		
	2022	2021	2020
	(in US\$'000)		
Goods—Marketed Products	14,407	15,792	11,329
Services—Commercialization—Marketed Products	41,275	27,428	3,734
-Collaboration Research and Development	8,054	4,491	1,991
Royalties	13,954	10,292	4,890
	77,690	58,003	21,944

## License and collaboration agreement with AstraZeneca

On December 21, 2011, the Group and AstraZeneca AB (publ) ("AZ") entered into a global licensing, codevelopment, and commercialization agreement for Orpathys ("AZ Agreement"), also known as savolitinib, a novel targeted therapy and a highly selective inhibitor of the c-Met receptor tyrosine kinase for the treatment of cancer. Under the terms of the AZ Agreement, the Group is entitled to receive a series of payments up to US\$140 million, including upfront payments and development and first-sale milestones. Additionally, the AZ Agreement contains possible significant future commercial sale milestones. Development costs for Orpathys in China will be shared between the Group and AZ, with the Group continuing to lead the development in China. AZ will lead and pay for the development of Orpathys for the rest of the world. Orpathys was successfully commercialized in China in July 2021, and the Group receives fixed royalties of 30% based on all sales in China. Should Orpathys be successfully commercialized outside China, the Group would receive tiered royalties from 9% to 13% on all sales outside of China.



In August 2016 (as amended in December 2020), the Group entered into an amendment to the AZ Agreement whereby the Group shall pay the first approximately US\$50 million of phase III clinical trial costs related to developing Orpathys for renal cell carcinoma ("RCC"), and remaining costs will be shared between the Group and AZ. Subject to approval of Orpathys in RCC, the Group would receive additional tiered royalties on all sales outside of China, with the incremental royalty rates determined based on actual sharing of development costs. In November 2021, the Group entered into an additional amendment which revised the sharing between the Group and AZ of development costs for Orpathys in China for non-small cell lung cancer, as well as adding potential development milestones.

Upfront and cumulative milestone payments according to the AZ Agreement received up to December 31, 2022 are summarized as follows:

	(in US\$'000)
Upfront payment	20,000
Development milestone payments achieved	40,000
First-sale milestone payment achieved	25,000

The AZ Agreement has the following performance obligations: (1) the license for the commercialization rights to Orpathys and (2) the research and development services for the specified indications. The transaction price includes the upfront payment, research and development cost reimbursements, milestone payments and sales-based royalties. Milestone payments were not included in the transaction price until it became probable that a significant reversal of revenue would not occur, which is generally when the specified milestone is achieved. The allocation of the transaction price to each performance obligation was based on the relative standalone selling prices 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 license to Orpathys and the research and development services were 95% and 5% respectively. Control of the license to Orpathys transferred at the inception date of the agreement and consequently, amounts allocated to this performance obligation were recognized at inception. Conversely, research and development services for each specified indication are performed over time and amounts allocated are recognized over time using the prior and estimated future development costs for Orpathys as a measure of progress.

Revenue recognized under the AZ Agreement and subsequent amendments is as follows:

	Year Ended December 31,		
	2022	2021	2020
		(in US\$'000)	
Goods—Marketed Products	9,904	6,509	—
Services—Collaboration Research and Development	14,467	14,113	7,780
Royalties	12,356	4,772	—
Licensing	14,954	23,661	—
	51,681	49,055	7,780

# 19. In-Licensing arrangement

On August 7, 2021, the Group and Epizyme, Inc. ("Epizyme") entered into a license agreement (the "Inlicense Agreement") for tazemetostat, a novel inhibitor of EZH2 that is approved by the U.S. Food and Drug Administration for the treatment of certain patients with epithelioid sarcoma and follicular lymphoma. The Group will be responsible for the development and commercialization of tazemetostat in the PRC, Hong Kong, Macau and Taiwan (the "Territory") and also holds rights to manufacture tazemetostat for the Territory. The Group also received a 4-year warrant, exercisable up to August 7, 2025, to purchase up to 5,653,000 shares of Epizyme common stock for an exercise price of US\$11.50 per share ("Warrant Exercise Price").

Under the terms of the In-license Agreement and warrant, the Group paid Epizyme a US\$25 million upfront payment and is obligated for a series of success-based payments up to US\$110 million in development and regulatory milestones and up to US\$175 million in sales milestones. Success-based payments are recognized when the related milestone is achieved. After tazemetostat is commercialized in the Territory, the Group will incur tiered royalties based on net sales. For the year ended December 31, 2022, US\$5.0 million development milestone was paid and expensed to research and development expenses as in-process research and development.



The US\$25 million upfront payment was first allocated to the warrant for its initial fair value of US\$15 million, and the remainder was allocated to the rights to tazemetostat which were expensed to research and development expense as in-process research and development.

The warrant was recorded as a financial asset at fair value with changes to fair value recognized to the consolidated statements of operations. On August 12, 2022, a third party announced that it has acquired all outstanding shares of Epizyme under a definitive merger agreement. Consequently, the warrant was deemed expired under the terms of the In-license Agreement and warrant. For the years ended December 31, 2022 and 2021, fair value losses of US\$2.5 million and US\$12.5 million were recognized to other expense in the consolidated statements of operations respectively.

# 20. Research and Development Expenses

Research and development expenses are summarized as follows:

	Yea	Year Ended December 31,		
	2022	2021	2020	
		(in US\$'000)		
Clinical trial related costs	255,935	190,051	105,869	
Personnel compensation and related costs	119,306	91,639	63,542	
Other research and development expenses	11,652	17,396	5,365	
	386,893	299,086	174,776	

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 years ended December 31, 2022, 2021 and 2020, the Group has incurred research and development expenses of US\$14,654,000, US\$18,408,000 and US\$8,291,000 respectively, related to such collaborative arrangements.

# 21. Government Grants

Government grants in the Oncology/Immunology segment are primarily given in support of the construction of a manufacturing plant in Shanghai and R&D activities which are conditional upon i) the Group spending a predetermined amount, regardless of success or failure of the research and development projects and/or ii) the achievement of certain stages of research and development projects being approved by the relevant PRC government authority. They are refundable to the government if the conditions, if any, are not met. Government grants in the Other Ventures segment are primarily given to promote local initiatives. These government grants may be subject to ongoing reporting and monitoring by the government over the period of the grant.

Government grants, which are deferred and recognized in the consolidated statements of operations over the period necessary to match them with the costs that they are intended to compensate, are recognized in other payables, accruals and advance receipts (Note 13) and other non-current liabilities. For the years ended December 31, 2022, 2021 and 2020, the Group received government grants of US\$8,474,000, US\$9,095,000 and US\$4,724,000 respectively.

Government grants were recognized in the consolidated statements of operations as follows:

	Yea	Year Ended December 31,		
	2022	2021	2020	
		(in US\$'000)		
Research and development expenses	4,556	15,515	1,607	
Other income	1,434	318	539	
	5,990	15,833	2,146	



# 22. Gain on divestment of an equity investee

In March 2021, the Group entered into a sale and purchase agreement (the "SPA") with a third party to sell its entire investment in HBYS with closing subject to regulatory approval in the PRC. On September 28, 2021, the Group completed the divestment for cash consideration of US\$159.1 million.

On May 13, 2021 and September 23, 2021, HBYS had declared dividends to shareholders of US\$46.5 million and US\$59.7 million respectively which were related to prior year undistributed profits and distributions of a land bonus payment. Based on the SPA, the Group is entitled to a portion of such dividends and the third party will settle these amounts, net of taxes, after HBYS completes the distribution. As at December 31, 2022 and 2021, US\$26.2 million and US\$46.4 million of dividend receivables, net of taxes, from the third party was recorded respectively in other receivables, prepayments and deposits (Note 7).

In addition, the Group and Hutchison Whampoa Enterprises Limited, an affiliate of CK Hutchison Holdings Limited ("CK Hutchison"), entered into a license agreement on June 15, 2021, conditional upon the completion of the divestment, to grant a continuing right to use the "Hutchison Whampoa" brand by HBYS for 10 years at HK\$12 million (approximately US\$1.5 million) per year with aggregate amounts not to exceed HK\$120 million (approximately US\$15.4 million). On September 28, 2021, the Group recorded the present value of future branding liability payments of US\$12.7 million. As at December 31, 2022 and 2021, US\$1.5 million was included in amounts due to related parties (Note 23(ii)) and US\$8.7 million and US\$9.8 million were included in other non-current liabilities respectively.

The gain on divestment of an equity investee was recognized in the consolidated statements of operations as follows:

	Year Ended December 31,
	2021
	(in US\$'000)
Proceeds	159,118
Dividend receivables-third party (Note 7)	46,387
	205,505
Less: Group's share of net assets of HBYS (Note 11(iii))	(23,246)
Dividend receivables-HBYS	(52,887)
Withholding tax liability on dividend receivables-HBYS	2,644
Branding liability	(12,721)
Accumulated other comprehensive income and reserves	1,911
Transaction costs and others	104
Gain on divestment of an equity investee	121,310
Less: Capital gain tax	(14,373)
Less: Gain on divestment of an equity investee attributable to non-controlling	
interests	(24,010)
Gain on divestment of an equity investee attributable to the Group	82,927

# 23. 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:

	Year Ended December 31,		
	2022	2021	2020
		(in US\$'000)	
Sales to:			
Indirect subsidiaries of CK Hutchison	3,610	4,256	5,484
An equity investee	1,683	—	—
	5,293	4,256	5,484
Revenue from research and development services from:			
An equity investee	507	525	491
Purchases from:			
Equity investees	4,231	3,770	3,347
Rendering of marketing services from:			
Indirect subsidiaries of CK Hutchison	227	350	332
An equity investee	127	—	—
	354	350	332
Rendering of management services from:			
An indirect subsidiary of CK Hutchison	980	971	955
Entered brand license agreement with:			
An indirect subsidiary of CK Hutchison (note (a))		12,721	

# (ii) Balances with related parties included in:

	December 31,	
	2022	2021
	(in US\$'000)	
Accounts receivable—related parties		
Indirect subsidiaries of CK Hutchison (note (b))	1,319	1,166
An equity investee (note (b))	2,198	—
	3,517	1,166
Other receivables, prepayments and deposits		
An equity investee (note (b))	998	1,149
Other payables, accruals and advance receipts		
Indirect subsidiaries of CK Hutchison (note (c) and (e))	1,953	1,915
An equity investee (note (b) and (d))	148	
	2,101	1,915
Other non-current liabilities		
An equity investee (note (d))	755	736
An indirect subsidiary of CK Hutchison (note (e))	8,716	9,766
	9,471	10,502

Notes:

- (a) The branding rights for HBYS from an indirect subsidiary of CK Hutchison were recognized in the consolidated statements of operations through the gain on divestment of an equity investee (Note 22). For the years ended December 31, 2022 and 2021, the Group paid US\$1,538,000 for each of the two years.
- (b) 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.

- (c) Amounts due to indirect subsidiaries of CK Hutchison are unsecured, repayable on demand and interestbearing if not settled within one month.
- (d) Other deferred income represents amounts recognized from granting of commercial, promotion and marketing rights.
- (e) As at December 31, 2022 and 2021, 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 December 31, 2022 and 2021, US\$8,716,000 and US\$9,766,000 of the branding liability payable was included in other non-current liabilities.

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

	Year Ended December 31,		
	2022	2021	2020
		(in US\$'000)	
Sales	47,611	41,974	36,500
Purchases	7,936	10,660	13,936
Dividends declared	25,600	9,894	1,462

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

	Deceml	December 31,	
	2022	2021	
	(in US	(in US\$'000)	
Accounts receivable	11,139	8,436	
Accounts payable	2,922	2,062	

# 24. Income Taxes

# (i) Income tax (benefit)/expense

	Yea	Year Ended December 31,		
	2022	2021	2020	
		(in US\$'000)		
Current tax				
HK (note (a))	301	310	457	
PRC (note (b) and (c))	2,580	15,909	872	
U.S. and others (note (d))	399	417	219	
Total current tax	3,280	16,636	1,548	
Deferred income tax (benefit)/expense	(3,563)	(4,718)	3,281	
Income tax (benefit)/expense	(283)	11,918	4,829	

Notes:

- (a) The Company, three subsidiaries incorporated in the British Virgin Islands and its Hong Kong subsidiaries are subject to Hong Kong profits tax. Under the Hong Kong two-tiered profits tax rates regime, the first HK\$2.0 million (US\$0.3 million) of assessable profits of qualifying corporations will be taxed at 8.25%, with the remaining assessable profits taxed at 16.5%. Hong Kong profits tax has been provided for at the relevant rates on the estimated assessable profits less estimated available tax losses, if any, of these entities as applicable.
- (b) Taxation in the PRC has been provided for at the applicable rate on the estimated assessable profits less estimated available tax losses, if any, in each entity. Under the PRC Enterprise Income Tax Law (the "EIT Law"), the standard enterprise income tax rate is 25%. In addition, the EIT Law provides for a preferential tax rate of 15% for companies which qualify as HNTE. HUTCHMED Limited and its wholly-owned subsidiary HUTCHMED (Suzhou) Limited qualify as a HNTE up to December 31, 2022 and 2023 respectively.

Pursuant to the EIT law, a 10% withholding tax is levied on dividends paid by PRC companies to their foreign investors. A lower withholding tax rate of 5% is applicable under the China-HK Tax Arrangement if direct foreign investors with at least 25% equity interest in the PRC companies are Hong Kong tax residents, and meet the conditions or requirements pursuant to the relevant PRC tax regulations regarding beneficial ownership. Since the equity holders of the equity investees of the Company are Hong Kong incorporated companies and Hong Kong tax residents, and meet the aforesaid conditions or requirements, the Company has used 5% to provide for deferred tax liabilities on retained earnings which are anticipated to be distributed. As at December 31, 2022, 2021 and 2020, the amounts accrued in deferred tax liabilities relating to withholding tax on dividends were determined on the basis that 100% of the distributable reserves of the equity investees operating in the PRC will be distributed as dividends.

Pursuant to PRC Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, an indirect transfer of a PRC resident enterprise by a non-PRC resident enterprise, via the transfer of an offshore intermediate holding company, shall be subject to PRC withholding tax under certain conditions.

- (c) Current tax in the PRC for the year ended December 31, 2021 includes US\$14.4 million arising from the indirect disposal of HBYS (Note 22), calculated at 10% of the excess of the disposal proceeds over the cost of acquiring the equity investment in HBYS.
- (d) The Company's subsidiary in the U.S. with operations primarily in New Jersey is subject to U.S. taxes, primarily federal and state taxes, which have been provided for at approximately 21% (federal) and 0% to 11.5% (state tax) on the estimated assessable profit over the reporting years. Certain income receivable by the Company is subject to U.S. withholding tax of 30%. Two of the Group's subsidiaries are subject to corporate tax in the UK and EU countries at 19% and 15% to 25%, respectively, on the estimated assessable profits in relation to their presence in these countries.

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

	Year Ended December 31,			
	2022 2021		2020	
		(in US\$'000)		
Loss before income taxes and equity in earnings of equity				
investees	(410,422)	(215,740)	(189,734)	
Tax calculated at the statutory tax rate of the Company	(67,720)	(35,597)	(31,306)	
Tax effects of:				
Different tax rates applicable in different jurisdictions	6,316	136	4,025	
Tax valuation allowance	93,243	63,975	46,321	
Preferential tax rate difference	(171)	(148)	(154)	
Preferential tax deduction and credits	(40,791)	(29,838)	(18,814)	
Expenses not deductible for tax purposes	8,886	8,684	3,476	
Withholding tax on undistributed earnings of PRC entities	2,492	3,153	3,962	
Others	(2,538)	1,553	(2,681)	
Income tax (benefit)/expense	(283)	11,918	4,829	

#### (ii) Deferred tax assets and liabilities

The significant components of deferred tax assets and liabilities are as follows:

	Decembe	er 31,
	2022	2021
	(in US\$'	000)
Deferred tax assets		
Cumulative tax losses	264,751	186,832
Others	15,254	12,269
Total deferred tax assets	280,005	199,101
Less: Valuation allowance	(264,639)	(189,700)
Deferred tax assets	15,366	9,401
Deferred tax liabilities		
Undistributed earnings from PRC entities	2,686	2,720
Others	24	45
Deferred tax liabilities	2,710	2,765

The movements in deferred tax assets and liabilities are as follows:

	2022	2021	2020
		(in US\$'000)	
As at January 1	6,636	(3,548)	(2,343)
Utilization of previously recognized withholding tax on			
undistributed earnings	2,186	5,148	2,323
(Charged)/Credited to the consolidated statements of			
operations			
Withholding tax on undistributed earnings of PRC entities	(2,492)	(3,153)	(3,962)
Deferred tax on amortization of intangible assets	19	19	18
Deferred tax on temporary differences, tax loss carried			
forward and research tax credits	6,036	7,852	663
Divestment of an equity investee		370	—
Exchange differences	271	(52)	(247)
As at December 31	12,656	6,636	(3,548)

The deferred tax assets and liabilities are offset when there is a legally enforceable right to set off and when the deferred income taxes relate to the same fiscal authority.



The cumulative tax losses can be carried forward against future taxable income and will expire in the following years:

	Decemb	er 31,
	2022	2021
	(in US\$	'000)
No expiry date	71,325	60,450
2022	—	200
2023	—	
2024	3,763	4,099
2025	36,098	39,321
2026	48,150	52,452
2027	61,808	67,217
2028	107,297	117,376
2029	175,853	191,554
2030	243,918	265,696
2031	389,761	432,278
2032	610,800	—
	1,748,773	1,230,643

The Company believes that it is more likely than not that future operations outside the U.S. will not generate sufficient taxable income to realize the benefit of the deferred tax assets. Certain of the Company's subsidiaries have had sustained tax losses, which will expire within five years if not utilized in the case of PRC subsidiaries (ten years for HNTEs), and which will not be utilized in the case of Hong Kong subsidiaries as they do not generate taxable profits. Accordingly, a valuation allowance has been recorded against the relevant deferred tax assets arising from the tax losses.

A U.S. subsidiary of the Company has approximately US\$3.9 million and US\$1.2 million U.S. Federal and New Jersey state research tax credits which will expire between 2041 and 2042 (Federal) and 2028 and 2029 (New Jersey) respectively, if not utilized.

The table below summarizes changes in the deferred tax valuation allowance:

	2022	2021	2020
		(in US\$'000)	
As at January 1	189,700	122,378	69,399
Charged to consolidated statements of operations	93,243	63,975	46,321
Utilization of previously unrecognized tax losses	(1)	(186)	(114)
Write-off of tax losses	(125)	—	_
Others	—	(9)	
Exchange differences	(18,178)	3,542	6,772
As at December 31	264,639	189,700	122,378

As at December 31, 2022, 2021 and 2020, the Group did not have any material unrecognized uncertain tax positions.

#### (iii) Income tax payable

	2022	2021	2020
		(in US\$'000)	
As at January 1	15,546	1,120	1,828
Current tax	3,280	16,636	1,548
Withholding tax upon dividend declaration from PRC			
entities	2,186	5,148	2,323
Tax paid (note)	(18,891)	(5,014)	(5,940)
Reclassification from non-current withholding tax	—	—	812
Reclassification (from)/to prepaid tax	(241)	25	485
Divestment of an equity investee (Note 22)	—	(2,644)	
Exchange difference	(768)	275	64
As at December 31	1,112	15,546	1,120

Note: The amount for 2022 includes US\$14.4 million capital gain tax paid for gain on divestment of HBYS (Note 22). The amount for 2020 is net of the PRC Enterprise Income Tax refund of US\$0.4 million received by HSPL.

## 25. Losses Per Share

#### (i) Basic losses per share

Basic losses per share is calculated by dividing the net loss attributable to the Company by the weighted average number of outstanding ordinary shares in issue during the year.

	Year Ended December 31,				
	2022	2021	2020		
Weighted average number of outstanding ordinary shares in					
issue	847,143,540	792,684,524	697,931,437		
Net loss attributable to the Company (US\$'000)	(360,835)	(194,648)	(125,730)		
Losses per share attributable to the Company (US\$ per					
share)	(0.43)	(0.25)	(0.18)		

#### (ii) Diluted losses per share

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

For the years ended December 31, 2022, 2021 and 2020, the share options, LTIP awards and warrants issued by the Company were not included in the calculation of diluted losses per share because of their antidilutive effect. Therefore, diluted losses per share were equal to basic losses per share for the years ended December 31, 2022, 2021 and 2020.

## 26. 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.



(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 (loss)/income attributable to the Company.

The segment information is as follows:

	Year Ended December 31, 2022							
		Onco	logy/Immunol	ogy				
		R&D		Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC (in US	Subtotal \$'000)	PRC	Unallocated	Total
Revenue from external customers	39,202	_	39,202	124,642	163,844	262,565	_	426,409
Interest income	674	4	678	_	678	272	8,649	9,599
Interest expense				—		_	(652)	(652)
Equity in earnings of equity investees, net of tax	5	_	5	_	5	49,748	_	49,753
Income tax (expense)/benefit	(552)	6,053	5,501	(631)	4,870	(1,345)	(3,242)	283
Net (loss)/income attributable to the Company	(215,834)	(186,945)	(402,779)	17,367	(385,412)	54,604	(30,027)	(360,835)
Depreciation/ amortization	(7,576)	(484)	(8,060)		(8,060)	(299)	(305)	(8,664)
Additions to non-current assets (other than financial instruments and deferred tax								
assets)	47,563	725	48,288		48,288	664	21	48,973

	December 31, 2022								
		Onco	logy/Immuna	logy					
				Marketed		Other			
		R&D		Products		Ventures			
		U.S. and							
	PRC	Others	Subtotal	PRC	Subtotal	PRC	Unallocated	Total	
				(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	

		Onco	logy/Immunol	ogy				
		R&D		Marketed Products		Other Ventures		
	PRC	U.S. and Others	Subtotal	PRC	Subtotal \$'000)	PRC	Unallocated	Total
Revenue from external				(11 03	<b>(\$ 000)</b>			
customers	43,181	_	43,181	76,429	119,610	236,518	_	356,128
Interest income	809	3	812		812	282	982	2,076
Interest expense	—		_	—	_	_	(592)	(592)
Equity in earnings of equity investees, net of tax	20	_	20	_	20	60,597	_	60,617
Income tax	20		20		20	00,001		00,017
benefit/(expense)	22	7,160	7,182	(1,320)	5,862	(14,573)	(3,207)	(11,918)
Net (loss)/income attributable to the	(1.10,500)							
Company	(143,528)	(152,235)	(295,763)	4,032	(291,731)	142,890	(45,807)	(194,648)
Depreciation/ amortization	(6,436)	(197)	(6,633)	_	(6,633)	(318)	(239)	(7,190)
Additions to non-current assets (other than financial instruments and deferred tax								
assets)	25,295	4,321	29,616		29,616	1,056	327	30,999

	December 31, 2021								
		Onco	logy/Immunc	logy					
				Marketed		Other			
		R&D		Products		Ventures			
		U.S. and							
	PRC	Others	Subtotal	PRC	Subtotal	PRC	Unallocated	Total	
				(in	US\$'000)				
Total assets	166,802	19,870	186,672	35,978	222,650	225,898	924,113	1,372,661	
Property, plant and									
equipment	38,049	1,862	39,911	_	39,911	746	618	41,275	
Right-of-use assets	4,798	3,768	8,566	—	8,566	1,827	1,486	11,879	
Leasehold land	13,169	—	13,169	—	13,169	—		13,169	
Goodwill		—	—	—	—	3,380		3,380	
Other intangible asset		—	—	—	—	163		163	
Investments in equity									
investees	480		480		480	75,999		76,479	

	Year Ended December 31, 2020							
		Onco	logy/Immunol	ogy				
		R&D		Marketed Products		Other Ventures		
		U.S. and						
	PRC	Others	Subtotal	PRC	Subtotal	PRC	Unallocated	Total
-				(in US	\$`000)			
Revenue from external								
customers	10,262		10,262	19,953	30,215	197,761		227,976
Interest income	461		461	—	461	167	2,608	3,236
Interest expense	_		_	_	—	_	(787)	(787)
Equity in earnings of equity investees, net								
of tax	(97)	_	(97)		(97)	79,143	—	79,046
Income tax								
(expense)/benefit	(402)	642	240	(167)	73	(824)	(4,078)	(4,829)
Net (loss)/income attributable to the								
Company	(120,096)	(62,683)	(182,779)	7,282	(175,497)	72,785	(23,018)	(125,730)
Depreciation/								
amortization	(5,458)	(119)	(5,577)	—	(5,577)	(292)	(192)	(6,061)
Additions to non-current assets (other than financial instruments and deferred tax								
assets)	22,574	754	23,328		23,328	817	1,090	25,235

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\$55,433,000, US\$46,891,000, and US\$19,230,000 for the years ended December 31, 2022, 2021, and 2020 respectively.

A summary of customers which accounted for over 10% of the Group's revenue for the years ended December 31, 2022, 2021 and 2020 is as follows:

	Year	Year Ended December 31,		
	2022	2022 2021		
		(in US\$'000)		
Customer A	75,606	56,082	(note)	
Customer B	51,681	49,055	(note)	
Customer C	47,611	41,974	36,500	
Customer D	(note)	(note)	25,993	

Note: Customer did not account for over 10% of the Group's revenue during the year.

Customer A and B are included in Oncology/Immunology and Customer C and D are primarily included in Other Ventures.

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



## 27. Note to Consolidated Statements of Cash Flows

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

	Year Ended December 31,		
	2022	2021	2020
		(in US\$'000)	
Net loss	(360,386)	(167,041)	(115,517)
Adjustments to reconcile net loss to net cash used in			
operating activities			
Depreciation and amortization	8,664	7,190	6,061
Amortization of finance costs	18	44	43
Loss on disposals of property, plant and equipment	111	70	85
Provision for excess and obsolete inventories	293	(23)	65
Provision for credit losses, net	43	(76)	77
Share-based compensation expense—share options	6,736	16,365	8,737
Share-based compensation expense—LTIP	23,850	25,625	10,905
Equity in earnings of equity investees, net of tax	(49,753)	(60,617)	(79,046)
Dividends received from SHPL and HBYS	43,718	49,872	86,708
Impairment of investment in other equity investee	130	—	—
Changes in right-of-use assets	2,721	(3,727)	(2,197)
Fair value losses on warrant	2,452	12,548	—
Gain from divestment of HBYS	—	(121,310)	—
Unrealized currency translation loss/(gain)	13,274	(2,505)	(6,149)
Changes in income tax balances	(19,174)	6,904	(1,111)
Changes in working capital			
Accounts receivable	(14,451)	(35,634)	(4,693)
Other receivables, prepayments and deposits	12,072	(5,758)	(9,602)
Inventories	(21,213)	(16,002)	(3,623)
Accounts payable	29,938	9,565	7,651
Other payables, accruals and advance receipts	52,629	66,224	37,472
Lease liabilities	(2,701)	3,079	2,258
Deferred revenue	386	11,071	(158)
Other	2,044	(87)	(32)
Total changes in working capital	58,704	32,458	29,273
Net cash used in operating activities	(268,599)	(204,223)	(62,066)

## 28. 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 Seroguel 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\$36.4 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, Luve filed a Notice of Appeal to the Court of Appeal regarding the dismissal and the notice was accepted on November 8, 2022. A Court of Appeal hearing date has been set for June 2023. The legal proceedings are ongoing, no Award amounts have been received as at the issuance date of these consolidated financial statements and no Award amounts have been recognized and no adjustment has been made to Seroquel-related balances as at December 31, 2022. Such Seroquel-related balances include accounts receivable, long-term prepayment, accounts payable and other payables of US\$1.1 million, US\$0.5 million, US\$0.9 million and US\$1.2 million respectively.

### **29. Restricted Net Assets**

Relevant PRC laws and regulations permit payments of dividends by the Company's subsidiaries in the PRC only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. In addition, the Company's subsidiaries in the PRC are required to make certain appropriations of net after-tax profits or increases in net assets to the statutory surplus fund prior to payment of any dividends. In addition, registered share capital and capital reserve accounts are restricted from withdrawal in the PRC, up to the amount of net assets held in each subsidiary. As a result of these and other restrictions under PRC laws and regulations, the Company's subsidiaries in the PRC are restricted in their ability to transfer their net assets to the Group in terms of cash dividends, loans or advances, with restricted portions amounting to US\$0.1 million and US\$0.1 million as at December 31, 2022 and 2021 respectively, which excludes the Company's subsidiaries with a shareholders' deficit. Even though the Group currently does not require any such dividends, loans or advances from the PRC subsidiaries, for working capital and other funding purposes, the Group may in the future require additional cash resources from the Company's subsidiaries in the PRC due to changes in business conditions, to fund future acquisitions and development, or merely to declare and pay dividends to make distributions to shareholders.

In addition, the Group has certain investments in equity investees in the PRC, where the Group's equity in undistributed earnings amounted to US\$53.7 million and US\$54.4 million as at December 31, 2022 and 2021 respectively.

## **30. Subsequent Events**

The Group evaluated subsequent events through February 28, 2023, which is the date when the consolidated financial statements were issued.

On January 23, 2023, the Group and Takeda Pharmaceuticals International AG ("Takeda") entered into an exclusive out-licensing agreement (the "Agreement") to further the global development, commercialization and manufacturing of Fruquintinib outside Mainland China, Hong Kong and Macau. The Group will receive up to US\$1,130.0 million from Takeda, including upfront payments of US\$400.0 million upon closing of the Agreement, as well as potential regulatory, development and commercial sales milestone payments, plus royalties on net sales.



## 31. Additional Information: Company Balance Sheets (Parent Company Only)

		Decem	ber 31,	
	Note	2022	2021	
		(in US	\$'000)	
Assets				
Current assets				
Cash and cash equivalents		7,892	979	
Short-term investments			55,128	
Other receivables, prepayments and deposits		947	934	
Total current assets		8,839	57,041	
Investments in subsidiaries		726,430	972,831	
Total assets		735,269	1,029,872	
Liabilities and shareholders' equity Current liabilities				
Other payables, accruals and advance receipts		124,178	42,952	
Income tax payable		16	16	
Total current liabilities		124,194	42,968	
Other non-current liabilities		708	11	
Total liabilities		124,902	42,979	
Commitments and contingencies	15	,	,	
Company's shareholders' equity				
Ordinary shares; \$0.10 par value; 1,500,000,000 shares authorized; 864,775,340 and 864,530,850 shares issued at December 31,				
2022 and 2021 respectively	16	86,478	86,453	
Additional paid-in capital		1,497,273	1,505,196	
Accumulated losses		(971,481)	(610,328)	
Accumulated other comprehensive (loss)/income		(1,903)	5,572	
Total Company's shareholders' equity		610,367	986,893	
Total liabilities and shareholders' equity		735,269	1,029,872	

## 32. Dividends

No dividend has been declared or paid by the Company since its incorporation.

## 33. Directors' Remuneration

Directors' remuneration disclosed pursuant to the Listing Rules, Section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Year	Year Ended December 31,			
	2022	2021	2020		
		(in US\$'000)			
Fees:	683	883	848		
Other remuneration					
Salaries, allowances and benefits in kind	1,173	1,160	1,093		
Pension contributions	98	93	89		
Performance related bonuses	1,587	2,245	2,005		
Share-based compensation expenses (note)	2,036	5,553	3,336		
	4,894	9,051	6,523		
	5,577	9,934	7,371		

Note: During the years ended December 31, 2022, 2021 and 2020, certain directors were granted share options and LTIP awards in respect of their services to the Group under the share option schemes and LTIP of the Company, further details of which are set out in Note 17. The share-based compensation expenses were recognized in the consolidated statements of operations during the years ended December 31, 2022, 2021 and 2020.



#### (i) Independent non-executive directors

The fees paid to independent non-executive directors were as follows:

	Year	Year Ended December 31,		
	2022	2021 (in US\$'000)	2020	
Paul Carter	117	117	117	
Karen Ferrante	103	103	103	
Graeme Jack	111	111	104	
Tony Mok	103	99	84	
	434	430	408	

The share-based compensation expenses of the independent non-executive directors were as follows:

	Year	Year Ended December 31,		
	2022	2021	2020	
		(in US\$'000)		
Paul Carter	139	91	73	
Karen Ferrante	139	91	73	
Graeme Jack	139	91	73	
Tony Mok	139	91	73	
	556	364	292	

There were no other remunerations payable to independent non-executive directors during the years ended December 31, 2022, 2021 and 2020.

#### (ii) Executive directors and non-executive directors

	Year Ended December 31, 2022					
	Fees	Salaries, allowances and benefits in kind	Pension <u>contributions</u> (in US\$	Performance related <u>bonuses</u> '000)	Share-based compensation	Total
Executive directors			•	ŕ		
Simon To	85				139	224
Wei-guo Su	75	706	64	1,127	1,650	3,622
Johnny Cheng	75	340	29	442	732	1,618
Christian Hogg (note)	14	127	5	18	(1,319)	(1,155)
	249	1,173	98	1,587	1,202	4,309
Non-executive directors						
Dan Eldar					139	139
Edith Shih	—		—		139	139
					278	278
	249	1,173	98	1,587	1,480	4,587

	Year Ended December 31, 2021					
	Fees	Salaries, allowances and benefits in kind	Pension contributions	Performance related bonuses	Share-based compensation	Total
		(in US\$'000)				
Executive directors						
Simon To	85	—	—		92	177
Wei-guo Su	75	412	35	835	1,934	3,291
Johnny Cheng	72	328	28	410	733	1,571
Christian Hogg (note)	77	420	30	1,000	2,246	3,773
	309	1,160	93	2,245	5,005	8,812
Non-executive directors						
Dan Eldar	70				92	162
Edith Shih	74		_		92	166
	144				184	328
	453	1,160	93	2,245	5,189	9,140

	Year Ended December 31, 2020					
	Fees	Salaries, allowances and benefits in kind	Pension <u>contributions</u> (in US\$	Performance related bonuses 2000)	Share-based compensation	Total
Executive directors			( ·	,		
Simon To	80	_	_	_	73	153
Wei-guo Su	75	362	32	736	1,472	2,677
Johnny Cheng	70	320	27	372	341	1,130
Christian Hogg (note)	75	411	30	897	1,012	2,425
	300	1,093	89	2,005	2,898	6,385
Non-executive directors						
Dan Eldar	70				73	143
Edith Shih	70				73	143
	140		_	_	146	286
	440	1,093	89	2,005	3,044	6,671

Note: Mr Christian Hogg retired as executive director on March 4, 2022.

## 34. Five Highest-Paid Employees

The five highest-paid employees during years ended December 31, 2022, 2021 and 2020 included the following number of directors and non-directors:

	Year	Year Ended December 31,		
	2022	2021	2020	
Directors	2	3	3	
Non-directors	3	2	2	
	5	5	5	

Details of the remuneration for the years ended December 31, 2022, 2021 and 2020 of the five highest-paid employees who are non-directors (the "Non-director Individuals") were as follows:

	Year	Year Ended December 31,		
	2022	2021 (in US\$'000)	2020	
Salaries, allowances and benefits in kind	1,497	859	715	
Pension contributions	51	52	48	
Performance related bonuses	1,759	802	735	
Share-based compensation expenses (note)	2,001	1,465	1,104	
	5,308	3,178	2,602	

Note: During the years ended December 31, 2022, 2021 and 2020, the Non-director Individuals were granted share options and LTIP awards in respect of their services to the Group under the share option schemes and LTIP of the Company, further details of which are set out in Note 17. The share-based compensation expenses

were recognized in the consolidated statements of operations during the years ended December 31, 2022, 2021 and 2020.

The number of Non-director Individuals whose remuneration fell within the following bands is as follows:

	Year	Year Ended December 31,		
	2022	2021	2020	
HK\$10,000,000 to HK\$10,500,000			2	
HK\$12,000,000 to HK\$12,500,000	2	1	_	
HK\$12,500,000 to HK\$13,000,000	—	1	—	
HK\$16,500,000 to HK\$17,000,000	1		—	
	3	2	2	

During the years ended December 31, 2022, 2021 and 2020, no remuneration was paid by the Group to any directors or Non-director Individuals as an inducement to join the Group or as compensation for loss of office. Additionally, none of the directors or Non-director Individuals have waived any remuneration during the years ended December 31, 2022, 2021 and 2020.

# 35. Reconciliation between U.S. GAAP and International Financial Reporting Standards

These 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 consolidated statements of operations

	Year Ended December 31, 2022 IFRS adjustments							
	Amounts as reported under U.S. GAAP	Lease amortization (note (a))	Issuance costs (note (b))	Capitalization of rights (note (c))	Divestment of an equity investee (note (d))	Amounts under IFRS		
Costs of goods—third parties	(268,698)	57	(in u	IS\$'000) 	_	(268,641)		
Research and development expenses	(386,893)	31		5,000		(381,862)		
Selling expenses	(43,933)	49				(43,884)		
Administrative expenses	(92,173)	182				(91,991)		
Total operating expenses	(834,102)	319		5,000		(828,783)		
Interest expense	(652)	(322)				(974)		
Other expense	(13,509)	12				(13,497)		
Total other (expense)/income	(2,729)	(310)				(3,039)		
Loss before income taxes and equity in earnings of equity investees	(410,422)	9	_	5,000		(405,413)		
Equity in earnings of equity investees, net of tax	49,753	(16)				49,737		
Net loss	(360,386)	(7)		5,000		(355,393)		
Less: Net income attributable to non- controlling interests Net loss attributable to the	(449)	(5)				(454)		
Company	(360,835)	(12)	_	5,000		(355,847)		

	Year Ended December 31, 2021 IFRS adjustments							
	Amounts as			Conitalization	Divestment of			
	reported under	Lease amortization	Issuance costs	Capitalization of rights	an equity investee	Amounts		
	U.S. GAAP	(note (a))	(note (b))	(note (c))	(note (d))	under IFRS		
		(1000 (0))		S\$'000)	(1000 (0))			
Costs of goods—third parties	(229,448)	40				(229,408)		
Research and development expenses	(299,086)	23		11,111		(287,952)		
Selling expenses	(37,827)	53				(37,774)		
Administrative expenses	(89,298)	161	(163)			(89,300)		
Total operating expenses	(684,445)	277	(163)	11,111		(673,220)		
Gain on divestment of an equity								
investee	121,310	—		—	11,266	132,576		
Interest expense	(592)	(400)				(992)		
Other expense	(12,643)	9				(12,634)		
Total other (expense)/income	(8,733)	(391)				(9,124)		
Loss before income taxes and	·							
equity in earnings of equity								
investees	(215,740)	(114)	(163)	11,111	11,266	(193,640)		
Income tax benefit/(expense)	(11,918)			_	370	(11,548)		
Equity in earnings of equity investees,								
net of tax	60,617	(1)	_	—	(11,636)	48,980		
Net loss	(167,041)	(115)	(163)	11,111	_	(156,208)		
Less: Net income attributable to non-								
controlling interests	(27,607)	(2)		(27)		(27,636)		
Net loss attributable to the								
Company	(194,648)	(117)	(163)	11,084		(183,844)		

	Year Ended December 31, 2020							
	Amounts as reported under U.S. GAAP	Lease amortization (note (a))	Issuance costs (note (b))	justments Capitalization of rights (note (c))	Divestment of an equity investee (note (d))	Amounts under IFRS		
Costs of goods—third parties	(178,828)	29	(in l	JS\$'000) 	_	(178,799)		
Research and development expenses	(174,776)	18				(174,758)		
Selling expenses	(11,334)	51				(11,283)		
Administrative expenses	(50,015)	132	860			(49,023)		
Total operating expenses	(424,644)	230	860	_	_	(423,554)		
Interest expense	(787)	(237)				(1,024)		
Other expense	(115)	15				(100)		
Total other (expense)/income	6,934	(222)	_	_		6,712		
Loss before income taxes and equity in earnings of equity investees	(189,734)	8	860	_		(188,866)		
Equity in earnings of equity investees, net of tax	79,046	4				79,050		
Net loss	(115,517)	12	860	_		(114,645)		
Less: Net income attributable to non- controlling interests	(10,213)	17	_	_	_	(10,196)		
Net loss attributable to the Company	(125,730)	29	860			(124,841)		

## (ii) Reconciliation of consolidated balance sheets

	December 31, 2022						
	Amounts as IFRS adjustments						-
	Amounts as reported under U.S. GAAP	Lease amortization (note (a))	Issuance costs (note (b))	Capitalization of rights (note (c)) (in US\$'000)	of an equity investee (note (d))	LTIP classification (note (e))	Amounts under IFRS
Right-of-use assets	8,722	(233)			_	_	8,489
Investments in equity investees	73,777	(37)				_	73,740
Other non-current assets	15,745			15,370			31,115
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)/income	(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

	December 31, 2021						
		_					
	Amounts as reported under U.S. GAAP	Lease amortization (note (a))	Issuance costs (note (b))	Capitalization of rights (note (c)) (in US\$'000)	Divestment of an equity investee (note (d))	LTIP classification (note (e))	Amounts under IFRS
Right-of-use assets	11,879	(257)	—		_	_	11,622
Investments in equity investees	76,479	(24)					76,455
Other non-current assets	21,551			11,296			32,847
Total assets	1,372,661	(281)	_	11,296		_	1,383,676
Other payables, accruals and advance receipts	210,839	_			_	(12,836)	198,003
Total current liabilities	311,658	_			_	(12,836)	298,822
Total liabilities	333,147					(12,836)	320,311
Additional paid-in capital	1,505,196	_	(697)	_	_	12,836	1,517,335
Accumulated losses	(610,328)	(233)	697	11,084			(598,780)
Accumulated other							
comprehensive (loss)/income	5,572	(7)		185	_	_	5,750
Total Company's							
shareholders' equity	986,893	(240)		11,269	_	12,836	1,010,758
Non-controlling interests	52,621	(41)		27			52,607
Total shareholders' equity	1,039,514	(281)		11,296		12,836	1,063,365

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 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) Divestment of HBYS

Under U.S. GAAP, an equity method investment to be divested that does not qualify for discontinued operations reporting would not qualify for held-for-sale classification. The investment in HBYS was not presented as a discontinued operation or as an asset classified as held-for-sale after the signing of the SPA in March 2021 and therefore, it was accounted for under the equity method until closing on September 28, 2021.

Under IFRS, an equity method investment may be classified as held-for-sale even if the discontinued operations criteria are not met. The investment in HBYS was not presented as a discontinued operation but was classified as held-for-sale and therefore equity method accounting was discontinued in March 2021 on the initial classification as held-for-sale. Accordingly, the reconciliation includes a classification difference in the consolidated statement of operations between gain on divestment of an equity investee, equity earnings of equity investees, net of tax and income tax expense.

#### (e) 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.