Zai Lab Limited
再鼎醫藥有限公司 *
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 9688)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2022

Zai Lab Limited together with its subsidiaries (collectively, the "**Company**", "**Zai Lab**", "**we**", or "**us**") hereby announces the unaudited condensed consolidated results of the Company for the six months ended June 30, 2022 (the "**Reporting Period**"), together with the comparative figures for the corresponding period in 2021, which have been prepared in accordance with generally accepted accounting principles in the United States (the "**U.S. GAAP**") and reviewed by the audit committee (the " **Audit Committee**") of the board of directors (the "**Board**") of the Company.

FINANCIAL HIGHLIGHTS

Six months ended June 30, 2022 vs. six months ended June 30, 2021 (in U.S. dollars ("$"))

- Total revenues increased by $37.9 million, or 66.4%, to $94.9 million. Product revenue increased by $36.6 million, or 64.2%, to $93.7 million. Collaboration revenue increased by $1.2 million from nil.
- Total expenses decreased by $181.3 million, or 39.9%, to $273.4 million.
- Research and development expenses decreased by $226.1 million, or 65.3%, to $119.9 million.
- Net loss decreased by $175.9 million, or 44.4%, to $220.3 million.
- Basic and diluted loss per share were $0.23 million, a decrease of 47.7% from $0.44 million.

UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands of $ except for number of shares and per share data)

	Notes	June 30, 2022 $	December 31, 2021 $
Assets			
Current assets:			
Cash and cash equivalents	3	**680,820**	964,100
Short-term investments		**575,274**	445,000
Accounts receivable (net of allowance for credit loss of $8 and $11 as of June 30, 2022 and December 31, 2021, respectively)	4	**27,054**	47,474
Notes receivable		**10,968**	7,335
Inventories, net	5	**23,339**	18,951
Value added tax recoverable — current		**219**	—
Prepayments and other current assets		**17,973**	18,021
Total current assets		**1,335,647**	1,500,881
Restricted cash, non-current		**803**	803
Long term investments (including the fair value measured investment of $2,827 and $15,383 as of June 30, 2022 and December 31, 2021, respectively)		**2,827**	15,605
Prepayments for equipment		**4,542**	989
Property and equipment, net	6	**46,419**	43,102
Operating lease right-of-use assets		**18,596**	14,189
Land use rights, net		**7,286**	7,811
Intangible assets, net		**1,673**	1,848
Long-term deposits		**947**	870
Value added tax recoverable		**37**	23,858
Total assets		**1,418,777**	1,609,956

	Notes	June 30, 2022 $	December 31, 2021 $
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable	7	**108,443**	126,163
Current operating lease liabilities		**6,824**	5,927
Other current liabilities	10	**53,610**	60,811
Total current liabilities		**168,877**	192,901
Deferred income		**24,775**	27,486
Non-current operating lease liabilities		**12,960**	9,613
Total liabilities		**206,612**	230,000
Commitments and contingencies (Note 16)			
Shareholders' equity			
Ordinary shares (par value of $0.000006 per share; 5,000,000,000 shares authorized; 960,520,140 and 955,363,980 shares issued as of June 30, 2022 and December 31, 2021, respectively; 958,494,830 and 954,981,050 shares outstanding as of June 30, 2022 and December 31, 2021, respectively)		**6**	6
Additional paid-in capital		**2,857,202**	2,825,948
Accumulated deficit		**(1,638,401)**	(1,418,074)
Accumulated other comprehensive income (loss)		**4,487**	(23,645)
Treasury Stock (at cost, 2,025,310 and 382,930 shares as of June 30, 2022 and December 31, 2021, respectively)		**(11,129)**	(4,279)
Total shareholders' equity		**1,212,165**	1,379,956
Total liabilities and shareholders' equity		**1,418,777**	1,609,956

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

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands of $ except for number of shares and per share data)

	Notes	Six Months Ended June 30, 2022 $	2021 $
Revenues:			
Product revenue, net	8	**93,670**	57,038
Collaboration revenue	8	**1,230**	—
Total revenues		**94,900**	57,038
Expenses:			
Cost of sales		**(33,051)**	(18,373)
Research and development		**(119,938)**	(346,076)
Selling, general, and administrative		**(120,392)**	(90,252)
Loss from operations		**(178,481)**	(397,663)
Interest income		**1,363**	458
Other income (expenses), net		**(42,988)**	1,179
Loss before income tax and share of loss from equity method investment		**(220,106)**	(396,026)
Income tax expense	9	**—**	—
Share of loss from equity method investment		**(221)**	(208)
Net loss		**(220,327)**	(396,234)
Net loss attributable to ordinary shareholders		**(220,327)**	(396,234)
Loss per share — basic and diluted	11	**(0.23)**	(0.44)
Weighted-average shares used in calculating net loss per ordinary share — basic and diluted		**956,603,250**	907,231,320
Loss per American Depositary Shares ("**ADS**") — basic and diluted		**(2.30)**	(4.37)
Weighted-average ADSs used in calculating net loss per ADS — basic and diluted		**95,660,325**	90,723,132

Note: All the numbers of ordinary shares and per share data in these unaudited condensed consolidated financial statements have been retrospectively adjusted as a result of the Share Subdivision and the ADS Ratio Change that became effective on March 30, 2022. The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company. Refer to Note 2(a) for a detailed discussion.

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

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands of $ except for number of shares and per share data)

	Six Months Ended June 30,	
	2022	2021
	$	$
Net loss	**(220,327)**	(396,234)
Other comprehensive income (loss), net of tax of nil:		
Foreign currency translation adjustments	**28,132**	(2,341)
Comprehensive loss	**(192,195)**	(398,575)

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

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands of $ except for number of shares and per share data)

	Ordinary Shares					Treasury Stock		
	Number of Shares	Amount $	Additional paid in capital $	Accumulated deficit $	Accumulated other comprehensive (loss) income $	Shares	Amount $	Total $
Balance at December 31, 2021	**955,363,980**	**6**	**2,825,948**	**(1,418,074)**	**(23,645)**	**(382,930)**	**(4,279)**	**1,379,956**
Issuance of ordinary shares upon vesting of restricted shares	**1,198,500**	**0**	**0**	**—**	**—**	**—**	**—**	**—**
Exercise of shares options	**3,957,660**	**0**	**4,619**	**—**	**—**	**—**	**—**	**4,619**
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	**—**	**—**	**—**	**—**	**—**	**(1,642,380)**	**(6,850)**	**(6,850)**
Share-based compensation	**—**	**—**	**26,635**	**—**	**—**	**—**	**—**	**26,635**
Net loss	**—**	**—**	**—**	**(220,327)**	**—**	**—**	**—**	**(220,327)**
Foreign currency translation	**—**	**—**	**—**	**—**	**28,132**	**—**	**—**	**28,132**
Balance at June 30, 2022	**960,520,140**	**6**	**2,857,202**	**(1,638,401)**	**4,487**	**(2,025,310)**	**(11,129)**	**1,212,165**
Balance at December 31, 2020	878,110,260	5	1,897,467	(713,603)	(14,524)	—	—	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	1,137,000	0	0	—	—	—	—	—
Exercise of shares options	5,488,810	0	3,991	—	—	—	—	3,991
Issuance of ordinary shares in connection with collaboration and license arrangement	5,681,820	0	62,250	—	—	—	—	62,250
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $879	57,164,000	1	817,995	—	—	—	—	817,996
Issuance cost adjustment for secondary listing	—	—	65	—	—	—	—	65
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	—	—	—	—	—	(60,860)	(924)	(924)
Share-based compensation	—	—	17,550	—	—	—	—	17,550
Net loss	—	—	—	(396,234)	—	—	—	(396,234)
Foreign currency translation	—	—	—	—	(2,341)	—	—	(2,341)
Balance at June 30, 2021	947,581,890	6	2,799,318	(1,109,837)	(16,865)	(60,860)	(924)	1,671,698

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. "0" in above table means less than 1,000 dollars.

UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands of $ except for number of shares and per share data)

	Six Months Ended June 30,	
	2022	2021
	$	$
Operating activities		
Net loss	**(220,327)**	(396,234)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for credit loss	**(3)**	4
Inventory write-down	**193**	290
Depreciation and amortization expenses	**3,874**	2,975
Amortization of deferred income	**(1,386)**	(156)
Share-based compensation	**26,635**	17,550
Noncash research and development expenses	**—**	62,250
Share of loss from equity method investment	**221**	208
Loss from fair value changes of equity investment with readily determinable fair value	**12,556**	—
(Gain) loss on disposal of property and equipment	**(11)**	4
Noncash lease expenses	**3,824**	2,779
Changes in operating assets and liabilities:		
Accounts receivable	**20,422**	(12,868)
Notes receivable	**(3,633)**	—
Inventories	**(4,582)**	1,740
Prepayments and other current assets	**48**	(1,953)
Long-term deposits	**(78)**	(29)
Value added tax recoverable	**23,602**	(1,682)
Accounts payable	**(17,718)**	62,980
Other current liabilities	**29,510**	28,078
Operating lease liabilities	**(3,849)**	(2,214)
Deferred income	**(1,325)**	930
Net cash used in operating activities	**(132,027)**	(235,348)
Cash flows from investing activities:		
Purchases of short-term investments	**(260,274)**	—
Proceeds from maturity of short-term investment	**130,000**	743,902
Purchase of property and equipment	**(13,488)**	(5,647)
Purchase of intangible assets	**(107)**	(427)
Net cash (used in) provided by investing activities	**(143,869)**	737,828

	Six Months Ended June 30,	
	2022	2021
	$	$
Cash flows from financing activities:		
Proceeds from exercises of stock options	**4,619**	3,992
Proceeds from issuance of ordinary shares upon public offerings	**—**	818,874
Payment of public offering costs	**—**	(1,323)
Employee taxes paid related to net share settlement of equity awards	**(6,859)**	(594)
Net cash (used in) provided by financing activities	**(2,240)**	820,949
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	**(5,144)**	1,028
Net (decrease) increase in cash, cash equivalents and restricted cash	**(283,280)**	1,324,457
Cash, cash equivalents and restricted cash — beginning of period	**964,903**	442,859
Cash, cash equivalents and restricted cash — end of period	**681,623**	1,767,316
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	**1,661**	1,720
Payables for intangible assets	**270**	58
Payables for public offering costs	**—**	555
Payables for treasury stock	**17**	—
Receivables for stock option exercise under equity incentive plans	**12**	—
Right-of-use asset acquired under operating leases	**8,451**	—
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	**680,820**	1,766,573
Restricted cash, non-current	**803**	743
Total cash and cash equivalents and restricted cash	**681,623**	1,767,316

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

NOTES TO THE UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and principal activities

Zai Lab Limited was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands (as amended). The Company are focused on developing and commercializing therapies that address medical conditions with unmet medical needs, including oncology, autoimmune disorders, infectious diseases, and neurological disorders.

The Company's principal operations and geographic markets are in Greater China. The Company has a substantial presence in Greater China and the United States.

2. Basis of presentation and consolidation and significant accounting policies

(a) Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("**U.S. GAAP**"), applicable rules and regulations of the U.S. Securities and Exchange Commission (the "**SEC**"), and the disclosure requirements of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time (the "**HK Listing Rules**"), regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP and HK Listing Rules have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this announcement should be read in conjunction with the consolidated financial statements and accompanying notes included in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022 (the "**2021 Annual Report**"). The December 31, 2021 condensed consolidated balance sheet data included in this announcement were derived from the audited financial statements included in the 2021 Annual Report.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year ending December 31, 2022.

Effective as of March 30, 2022, the Company subdivided each of its issued and unissued ordinary shares into ten ordinary shares (the "**Share Subdivision**"). Following the Share Subdivision, the Company's authorized share capital became $30,000 divided into 5,000,000,000 shares with a par value of US$0.000006 per share. The numbers of issued and unissued ordinary shares and per share data as disclosed elsewhere in these unaudited condensed consolidated financial statements and notes thereto are presented on a basis after taking into account the effects of the Share Subdivision and have been retrospectively adjusted, where applicable. In connection with the Share Subdivision, the conversion ratio of our ADSs to ordinary shares changed from one ADS to one ordinary share to a new ratio of one ADS representing ten ordinary shares (the "**ADS Ratio Change**"). The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

(b) Principles of consolidation

The unaudited condensed consolidated financial statements include the financial statements of the Company. All intercompany transactions and balances among the Company are eliminated upon consolidation.

(c) Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, and assessing the impairment of long-lived assets, discount rate of operating lease liabilities, accrual of rebates, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets, and a lack of marketability discount of the ordinary shares issued in connection with collaboration and license arrangements (Note 14). Management bases its estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

(d) Fair value measurements

As of June 30, 2022 and December 31, 2021, information about inputs into the fair value measurement of the Company's assets that are measured at a fair value on a recurring basis in periods subsequent to their initial recognition is as follows (in thousands):

Description	Fair Value as of June 30, 2022 US$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US$
Equity Investments with Readily Determinable Fair Value	**2,827**	**2,827**

Description	Fair Value as of December 31, 2021 US$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US$
Equity Investments with Readily Determinable Fair Value	15,383	15,383

The Company did not have assets or liabilities measured at fair value on a nonrecurring basis during the periods presented.

Financial instruments of the Company primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities. As of June 30, 2022 and December 31, 2021, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximated its fair value based on the assessment of the ability to recover these amounts.

(e) Recent accounting pronouncements

Adopted accounting standards

In November 2021, the FASB issued ASU2021-10, Government Assistance (Topic 832) — Disclosures by Business Entities about Government Assistance. The amendments in this ASU require disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model to increase transparency about (1) the types of transactions, (2) the accounting for the transactions, and (3) the effect of the transactions on an entity's financial statements. The amendments in this ASU are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this standard as of January 1, 2022. There was no material impact to the Company's financial position or results of operations upon the adoption.

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the 2021 Annual Report.

3. Cash and cash equivalents

The following table presents the Company's cash and cash equivalents as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Cash at bank and in hand	**381,225**	663,472
Cash equivalents[(i)]	**299,595**	300,628
	680,820	964,100
Denominated in:		
US$	**611,478**	932,888
RMB[(ii)]	**63,359**	23,791
Hong Kong dollar ("**HK$**")	**5,138**	6,674
Australian dollar ("**A$**")	**614**	475
Taiwan dollar ("**TW$**")	**231**	272
	680,820	964,100

(i) Cash equivalents represent short-term and highly liquid investments in a money market fund.

(ii) Certain cash and bank balances denominated in RMB were deposited with banks in mainland China. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the Chinese government.

4. Accounts receivable

The following table presents the Company's accounts receivable as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Accounts receivable	**27,062**	47,485
Impairment	**(8)**	(11)
Total	**27,054**	47,474

The Company's trading terms with its customers are mainly on credit and the credit period generally ranges from 40 to 90 days. The Company seeks to maintain strict control over its outstanding receivables and overdue balances are regularly reviewed. The Company does not hold any collateral or other credit enhancements over its accounts receivable balances. Accounts receivable are non-interest-bearing.

The following table presents an aging analysis of the accounts receivable, based on the invoice date (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Within 3 months	**27,054**	47,474

5. Inventories, net

The Company's net inventory balance of $23.3 million and $19.0 million as of June 30, 2022 and December 31, 2021, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline ("**GSK**"), for distribution in Hong Kong, from NovoCure Limited ("**NovoCure**") for distribution in Hong Kong and mainland China, and from Deciphera Pharmaceuticals, LLC ("**Deciphera**") for distribution in Hong Kong, mainland China and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China. The following table presents the Company's inventories, net, as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Finished goods	**4,342**	5,632
Raw materials	**18,476**	13,231
Work in Progress	**521**	88
Inventories, net	**23,339**	18,951

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. During the six months ended June 30, 2022, the Company recorded write-downs of $0.2 million in cost of sales. During the six months ended June 30, 2021, the Company recorded write-downs of $0.3 million in cost of sales.

6. Property and equipment, net

The following table presents the Company's components of property and equipment, net as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Office equipment	**822**	836
Electronic equipment	**6,370**	5,036
Vehicle	**210**	220
Laboratory equipment	**18,593**	17,069
Manufacturing equipment	**13,984**	14,600
Leasehold improvements	**10,230**	10,432
Construction in progress	**15,343**	11,334
	65,552	59,527
Less: accumulated depreciation	**(19,133)**	(16,425)
Property and equipment, net	**46,419**	43,102

Depreciation expense was $3.6 million for the six months ended June 30, 2022, and $2.7 million for the six months ended June 30, 2021, respectively.

7. Accounts payable

The following table presents an aging analysis of the accounts payable as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Within 3 months	**107,498**	125,709
3 months to 6 months	**731**	416
6 months to 1 year	**199**	22
Over 1 year	**15**	16
Total	**108,443**	126,163

The accounts payable are non-interest-bearing and repayable within the normal operating cycle or on demand.

8. Revenue

Product revenue, net

The Company's product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The table below presents the Company's net product sales for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,	
	2022	2021
	$	$
Product revenue — gross	**107,649**	87,935
Less: Rebate and sales return	**(13,979)**	(30,897)
Product revenue — net	**93,670**	57,038

Sales rebates are offered to distributors in mainland China, and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories.

The Company lowered the selling price of ZEJULA due to its inclusion in the National Reimbursement Drug List ("**NRDL**") for certain therapies. Accordingly, the Company accrued $2.9 million for sales rebates as compensation to distributors in mainland China for those products previously sold at the price prior to the NRDL implementation during the six months ended June 30, 2022, and $22.0 million during the six months ended June 30, 2021.

In June 2022, the Company lowered the selling price for QINLOCK and NUZYRA. Accordingly, the Company accrued $2.9 million of sales rebates as compensation to distributors in mainland China for those products previously sold at the price prior to the reduction during the three months ended June 30, 2022.

The following table presents net revenue by product for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,	
	2022	2021
	$	$
ZEJULA	**63,649**	35,972
Optune	**24,389**	16,665
QINLOCK	**3,582**	4,401
NUZYRA	**2,050**	—
Product revenue — net	**93,670**	57,038

Collaboration revenue

The Company's collaboration revenue for the six months ended June 30, 2022 of $1.2 million was from its collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

9. Income Tax

No provision for income taxes has been required to be accrued because the Company is in cumulative loss positions for the periods presented.

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of June 30, 2022 and December 31, 2021. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

10. Other current liabilities

The following table presents the Company's other current liabilities as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Payroll	**18,976**	25,685
Accrued rebate to distributors	**11,249**	15,001
Tax payables	**9,896**	8,817
Accrued professional service fee	**6,450**	4,319
Other[(i)]	**5,827**	4,421
Payables for purchase of property and equipment	**1,212**	2,568
Total	**53,610**	60,811

(i) Other primarily consists of tax withholding related to share-based compensation and accrued travel and business entertainment expenses.

11. Loss per share

The following table presents the computation of the basic and diluted net loss per share for the six months ended June 30, 2022 and 2021 (in thousands, except share and per share data):

	Six Months Ended June 30,	
	2022	2021
	$	$
Numerator:		
Net loss attributable to ordinary shareholders	**(220,327)**	(396,234)
Denominator:		
Weighted average number of ordinary shares — basic and diluted	**956,603,250**	907,231,320
Net loss per share — basic and diluted	**(0.23)**	(0.44)

As a result of the Company's net loss for the six months ended June 30, 2022 and 2021, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	June 30,	June 30,
	2022	2021
Share options	**91,546,280**	86,294,400
Non-vested restricted shares	**34,356,250**	6,325,350

12. Related party transactions

The Company incurred research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd ("**MEDx**"), over which an immediate family member of our Chief Executive Officer and Chairperson of the Board held significant influence. The Company incurred development expenses with MEDx of $0.1 million during the six months ended June 30, 2022, and $0.2 million during the six months ended June 30, 2021, respectively.

13. Share-based compensation

In March 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "**2015 Plan**"), pursuant to which the Board of Directors could grant options to purchase ordinary shares to management including officers, directors, employees, and individual advisors who rendered services to the Company. In August 2017, in connection with the completion of the initial public offering (the "**IPO**") of the Company, the Board of Directors approved the 2017 Equity Incentive Plan (the "**2017 Plan**"). All equity-based awards subsequent to the IPO would be granted under the 2017 Plan. The 2017 Plan provided for an automatic annual

increase to the number of ordinary shares reserved under the 2017 Plan on each January 1st between January 1, 2018 and January 1, 2027 equal to the lesser of 4% of the number of ordinary shares outstanding as of the close of business on the immediately prior December 31st or such number as approved by the Board on or prior to such date each year. The aggregate number of shares reserved and available for issuance under the 2017 Plan as of April 1, 2022 was 75,562,170.

On June 22, 2022, at the 2022 Annual General Meeting of Shareholders of the Company (the "**Annual General Meeting**"), the Company's shareholders approved the 2022 Equity Incentive Plan (the "**2022 Plan**"), which was previously approved by the Company's Board of Directors on April 20, 2022, conditioned on and subject to (i) the dual primary listing of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the "**Hong Kong Stock Exchange**") and (ii) the granting of a waiver on Note 1 to Rule 17.03(9) of the HK Listing Rules. The Company's voluntary conversion of its secondary listing status to primary listing status on the Hong Kong Stock Exchange became effective on June 27, 2022, and the waiver was granted to the Company in connection with the primary conversion. As such, the 2022 Plan became effective on June 27, 2022, and the aggregate number of shares that may be delivered in satisfaction of awards under the 2022 Plan is 97,908,743 ordinary shares as of June 22, 2022. No new grants will be made under the 2015 Plan or the 2017 Plan as of the effective date of the 2022 Plan.

For the six months ended June 30, 2022, the Company granted 17,885,480 share options and 27,360,150 share of non-vested restricted shares to certain management and employees of the Company under the 2017 Plan. The share options were granted at an exercise price ranging from $2.95 to $6.29 per share with a weighted-average grant-date fair value of $2.84 per share.

The options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date. The restricted shares granted to employees vest over a five- or four-year period, with 20% or 25% of the awards vesting beginning on the anniversary date one year after the grant date. The restricted shares granted to independent directors will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the award holders' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

Upon each settlement date of the stock awards, shares were withheld to cover the required withholding tax, which was based on the value of a share on the settlement date as determined by the closing price of the ADSs on the trading day of the applicable settlement date. The remaining shares after the withholding were delivered to the recipient. The amount remitted to the tax authorities for employee tax obligations was reflected as a financing activity on the condensed consolidated statements of cash flows. These shares withheld by the Company as a result of the net settlement were accounted for as treasury stock and not considered outstanding.

Stock-based compensation expense has been reported in the Company's condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Six Months Ended June 30,	
	2022	2021
	$	$
Selling, general and administrative	**15,923**	10,432
Research and development	**10,712**	7,118
Total	**26,635**	17,550

As of June 30, 2022, there was unrecognized share-based compensation expense of $121.2 million related to unvested share options which the Company expects to recognize over a weighted-average period of 3.58 years.

As of June 30, 2022, there was unrecognized share-based compensation expense of $153.8 million related to unvested restricted shares which the Company expects to recognize over a weighted-average period of 3.91 years.

14. Licenses and collaborative arrangements pursuant to which milestone payments were made

The following is a description of the Company's significant ongoing collaboration agreements under which the Company has made milestone payments for the six months ended June 30, 2022.

Collaboration and license agreement with argenx BV ("argenx")

In January 2021, the Company entered into a collaboration and license agreement with argenx. The Company received an exclusive license to develop and commercialize products containing argenx's proprietary antibody fragment, known as efgartigimod, in Greater China. The Company is responsible for the development of the licensed compound and licensed product and will have the right to commercialize such licensed product in the territory.

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Company and argenx. As the upfront payment to argenx, the Company issued 5,681,820 ordinary shares of the Company with a par value of $0.000006 per share to argenx on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares were subject to certain restrictions. The fair value of the shares on the closing date was determined to be $62.3 million in the aggregate. In addition, the Company made a non-creditable, non-refundable development cost-sharing payment of $75.0 million to argenx during the first quarter of 2021. In January 2022, the Company made a milestone payment of $25.0 million to argenx due to the first regulatory approval by the U.S. Food and Drug Administration ("**FDA**") in December 2021 for VYVGART (efgartigimod alfa-fcab). The Company recorded these payments in research and development expenses. Argenx is also eligible to receive tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed product in the territory.

License and collaboration agreement with Paratek Bermuda Ltd. ("Paratek")

In April 2017, the Company entered into a license and collaboration agreement with Paratek Bermuda Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., pursuant to which it obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, and commercialize products containing omadacycline (ZL-2401) as an active ingredient in Greater China in the field of all human therapeutic and preventative uses other than biodefense. Under certain circumstances, the exclusive sub-license to certain intellectual property Paratek licensed from Tufts University may be converted to a non-exclusive license if Paratek's exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. The Company also obtained the right of first negotiation to be Paratek's partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek retains the right to manufacture the licensed product in our licensed territory to support development and commercialization of the product outside of our licensed territory. The Company also granted to Paratek a non-exclusive license to certain of our intellectual property. Under the agreement, the Company agreed not to commercialize certain competing products in our licensed territory.

Under the terms of the agreement, the Company made an upfront payment of $7.5 million to Paratek in 2017, a $5.0 million milestone payment upon approval by the FDA of a New Drug Application ("**NDA**") submission in 2018, and a $3.0 million milestone payment upon submission of the first regulatory approval application for a licensed product in mainland China in 2020. In February 2022, The Company made another milestone payment of $6.0 million upon regulatory approval of omadacycline for the treatment of adults with Acute Bacterial Skin and Skin Structure Infections and Community-Acquired Bacterial Pneumonia in mainland China in December 2021. The Company may be required to pay further commercial milestone payments of up to $40.5 million to Paratek for the achievement of certain development and sales milestone events. In addition, the Company will pay Paratek tiered royalties on the net sales of licensed products, until the later of the abandonment, expiration, or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Company has the right to terminate this agreement at any time by providing written notice of termination to Paratek.

Collaboration and license agreement with Mirati Therapeutics, Inc. ("Mirati")

In May 2021, the Company entered into a collaboration and license agreement with Mirati. The Company obtained the right to research, develop, manufacture, and exclusively commercialize adagrasib in Greater China. The Company will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRASG12C mutation. Mirati has an option to co-commercialize in Greater China and retains full and exclusive rights to adagrasib in all countries outside of Greater China.

Under the terms of the agreement, the Company paid an upfront payment of $65.0 million to Mirati in 2021. During the three months ended June 30, 2022, the Company accrued a development milestone payment of $5.0 million. Mirati is also eligible to receive up to $268.0 million in-development, regulatory, and sales-based milestone payments. Mirati is also eligible to receive tiered royalties (from high-teens to low-twenties on a percentage basis) based on annual net sales of adagrasib in Greater China.

The Company has the right to terminate this agreement at any time by providing written notice of termination to Mirati.

License agreement with Karuna Therapeutics, Inc. ("Karuna")

In November 2021, the Company entered into a license agreement with Karuna for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China, including China, Hong Kong, Macau, and Taiwan.

Under the terms of the agreement, the Company paid an upfront payment of $35.0 million to Karuna. During the three months ended June 30, 2022, the Company accrued a development milestone payment of $5.0 million. Karuna is also eligible to receive up to $147.0 million in development and regulatory, and sales-based milestone payments. Karuna is also eligible to receive tiered royalties based on annual net sales of commercialized products in Greater China.

The Company has the right to terminate this agreement by providing written notice of termination to Karuna.

Full details of the licenses and collaborative arrangements are included in the notes to the financial statements in our 2021 Annual Report. As noted above, the Company has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Company is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Company up to approximately $5,576.3 million in future contingent development and sales-based milestone payments. The development milestones, such as regulatory approval for the product candidates, may occur before the Company has commercialized the product or received any revenue from sales of such product candidate. These milestone payments are subject to uncertainties and contingencies and may not occur.

15. Restricted net assets

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its Chinese subsidiaries. Relevant Chinese laws and regulations permit payments of dividends by the Company's Chinese subsidiaries only out of its retained earnings, if any, as determined in accordance with Chinese accounting standards and regulations. The results of operations reflected in the unaudited condensed consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Company's Chinese subsidiaries.

In accordance with the Company Law of the People's Republic of China, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's Chinese statutory accounts. A domestic enterprise may provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's Chinese statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's Chinese subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

During the six months ended June 30, 2022 and 2021, no appropriation to statutory reserves was made because the Company's Chinese subsidiaries had substantial losses during such periods.

As a result of these Chinese laws and regulations, subject to the limits discussed above that require annual appropriations of 10% of after-tax profit to be set aside, prior to payment of dividends, as general reserve fund, the Company's Chinese subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulation in mainland China may further restrict the Company's Chinese subsidiaries from transferring funds to the Company in the form of dividends, loans, and advances. As of June 30, 2022 and December 31, 2021, amounts restricted are the paid-in capital of the Company's Chinese subsidiaries, which both amounted to $406.0 million.

16. Commitments and Contingencies

(a) Purchase commitments

As of June 30, 2022, the Company's commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statement were $19.5 million which is expected to be incurred within one year.

(b) Contingencies

The Company is a party to, or assignee of, license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 14).

17. Subsequent Event

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date financial statements were issued. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

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

The condensed consolidated financial statements are prepared in accordance with U.S. GAAP, which differ in certain respects from the International Financial Reporting Standards ("**IFRS**"). The effects of material differences on the financial information of the Company prepared under U.S. GAAP and IFRS are as follows (in thousands):

(i) Reconciliation of consolidated statements of operations

	Six months ended June 30, 2022		
Consolidated statements of operations	**Amounts as reported under U.S. GAAP**	**IFRS adjustments Share-based compensation (note (i))**	**Amounts as reported under IFRS**
Expenses			
Research and development	**(119,938)**	**(2,057)**	**(121,995)**
Selling, general and administrative	**(120,392)**	**(5,305)**	**(125,697)**
Net loss	**(220,327)**	**(7,362)**	**(227,689)**
Net loss attributable to ordinary shareholders	**(220,327)**	**(7,362)**	**(227,689)**

	Six months ended June 30, 2021		
Consolidated statements of operations	Amounts as reported under U.S. GAAP	IFRS adjustments Share-based compensation (note (i))	Amounts as reported under IFRS
Expenses			
Research and development	(346,076)	(2,330)	(348,406)
Selling, general and administrative	(90,252)	(3,407)	(93,659)
Net loss	(396,234)	(5,737)	(401,971)
Net loss attributable to ordinary shareholders	(396,234)	(5,737)	(401,971)

(ii) Reconciliation of consolidated balance sheets

	As at June 30, 2022		
Consolidated balance sheets	**Amounts as reported under U.S. GAAP**	**IFRS adjustments Share-based compensation (note (i))**	**Amounts as reported under IFRS**
Additional paid-in capital	**2,857,202**	**38,062**	**2,895,264**
Accumulated deficit	**(1,638,401)**	**(38,062)**	**(1,676,463)**
Total shareholders' equity	**1,212,165**	**—**	**1,212,165**

	As at December 31, 2021		
Consolidated balance sheets	Amounts as reported under U.S. GAAP	IFRS adjustments Share-based compensation (note (i))	Amounts as reported under IFRS
Additional paid-in capital	2,825,948	30,700	2,856,648
Accumulated deficit	(1,418,074)	(30,700)	(1,448,774)
Total shareholders' equity	1,379,956	—	1,379,956

Notes:

(i) Share based compensation

Under U.S. GAAP, the Company has elected to use the straight-line method to recognize compensation expense for instruments granted to employees with graded vesting based on service conditions, subject to the minimum amount of cumulative compensation expense recognized is not less than the portion of the award vested to date.

Under IFRS, the graded vesting method must be applied to recognize compensation expense.

In addition, under U.S. GAAP, the Company has elected to recognize the effect of forfeitures as they occur, and previously recognized compensation cost is reversed in the period that the award is forfeited.

Under IFRS, the number of instruments that are expected to vest are estimated by the Company initially. Subsequently, these estimates are trued up for differences between the number of instruments expected to vest and the actual number of instruments vested.

A difference of $7.4 million arose between the amount of share-based compensation (included in research and development expenses, and selling, general and administrative expenses) recognized under U.S. GAAP and IFRS for the six months ended June 30, 2022 (six months ended June 30, 2021: $5.7 million).

The accumulated difference on share-based compensation recognized in expenses and additional paid in capital under U.S. GAAP and IFRS was $38.1 million, and net impact on the accumulated deficit was $30.7 million as of December 31, 2021.

(ii) Lease

Under U.S. GAAP, as a lessee, the Company recognized a lease liability based on the present value of the total remaining lease payments, and a corresponding right of use asset. The amortization of the right-of-use assets and the interest expenses related to the lease liabilities are recorded together as a single total lease expense on a straight-line basis on the condensed consolidated statement of operations.

Under IFRS, the amortization of the right-of-use assets is recognized on a straight-line basis while the interest expense related to the lease liabilities is recognized on the basis that the lease liabilities are measured at amortized cost. Compared to the U.S. GAAP, this changes the allocation and the total amount of expenses recognized for each period of the lease terms, and results in a higher total charge to profit or loss in the early years and a decreasing expense during the latter years of the lease terms. The amortization on the right-of-use assets and the interest expense on the lease liabilities are separately recorded on the condensed consolidated statement of operations.

Based on the Company's assessment, the differences on lease recognized under U.S. GAAP and IFRS did not have material impact on the condensed consolidated financial statements as of June 30,2022 and December 31, 2021, respectively, and for the six months ended June 30, 2022 and 2021, respectively.

MANAGEMENT DISCUSSION AND ANALYSIS

Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company based in China and the United States. We are discovering, developing, and commercializing innovative products that target medical conditions with unmet needs affecting patients in Greater China and worldwide, in the areas of oncology, autoimmune disorders, infectious diseases, and neurological disorders. As of August 3, 2022, we have four commercialized products that have received marketing approval in one or more territories in Greater China and twelve programs in late–stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and to generate positive cash flow from operations over the next several years depends upon our ability to successfully market our four commercial products — ZEJULA, Optune, QINLOCK, and NUZYRA — and to successfully develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones as well as tiered royalties based on the net sales of the licensed products. These upfront and milestone payments are recorded in our research and development expense. During the six months ended June 30, 2022, we accrued $10.4 million of research and development expense related to the achievement of certain developmental milestones by our partners during the second quarter of 2022. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

Furthermore, as we pursue our strategy of growth and development, we anticipate that our financial results will fluctuate from quarter to quarter based upon the balance between the successful marketing of our commercial products and our significant research and development expenses. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

Recent Developments

Recent Product Developments

ZEJULA

In March 2022, we presented positive results from the Phase 3 PRIME study of ZEJULA (niraparib) as maintenance therapy at the Society of Gynecologic Oncology (SGO) 2022 Annual Meeting. ZEJULA demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) with a tolerable safety profile in Chinese patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (collectively termed as ovarian cancer) following a response to platinum-based chemotherapy, regardless of biomarker status. In the PRIME study, median PFS was significantly longer for patients treated with niraparib compared to placebo: 24.8 months versus 8.3 months, hazard ratio (HR), 0.45; p<0.001.

In June 2022, we presented a new prespecified subgroup analysis from the Phase 3 PRIME study for ZEJULA in women in mainland China with ovarian cancer at the 2022 American Society of Clinical Oncology ("ASCO") Annual Meeting. This analysis examined 384 newly diagnosed stage III or IV ovarian cancer patients enrolled in the PRIME study who experienced a complete response ("CR") or partial response ("PR") to first-line platinum-based chemotherapy. In the CR group, the median progression-free survival ("mPFS") was 29.4 months for niraparib vs 8.3 months for placebo (HR=0.45; 95% CI, 0.32–0.61; P<0.001); in the PR group, the mPFS was 19.3 months for niraparib versus 8.3 months for placebo (HR=0.45; 95% CI, 0.23–0.86; P=0.014); and the safety profile of niraparib was consistent with previous clinical trials, with no new safety issues identified in this subgroup analysis.

Optune

In January 2022, we announced treatment of the first patient in Greater China in the PANOVA-3 trial, a Phase 3 pivotal trial of Tumor Treating Fields in patients with pancreatic cancer. PANOVA-3 is a global, open-label, randomized Phase III trial evaluating the efficacy of TTFields administered concomitantly with gemcitabine and nab-paclitaxel as front-line treatment for patients with unresectable, locally advanced pancreatic cancer. The primary endpoint is overall survival. Secondary endpoints include progression-free survival, local progression-free survival, objective response rate, one-year survival rate, quality of life, pain-free survival, resectability rate and toxicity.

In June 2022, the Company and Novocure announced the EF-31 phase 2 pilot study, evaluating the safety and efficacy of TTFields together with standard-of-care (chemotherapy alone or in combination with trastuzumab for HER2-positive patients) as a first-line treatment in patients with gastric cancer, met its primary endpoint of objective response rate ("ORR") with supportive signals across secondary endpoints. As of June 30, 2022, Optune has been listed in 50 regional customized commercial health insurance plans guided by provincial or municipal governments (or "supplemental insurance plans").

QINLOCK

As of June 30, 2022, QINLOCK has been listed in 73 supplemental insurance plans since its commercial launch in mainland China in May 2021.

Adagrasib

At the ASCO Annual Meeting in June 2022, our partner Mirati Therapeutics, Inc. ("Mirati") presented full results from the registration-enabling Phase 2 cohort of the KRYSTAL-1 study evaluating adagrasib in patients with previously treated non-small cell lung cancer ("NSCLC") harboring a KRASG12C mutation; these results were concurrently published in the New England Journal of Medicine. This presentation included results from a retrospective subgroup analysis from the Phase 2 NSCLC cohort of the KRYSTAL-1 study evaluating adagrasib in patients with KRASG12C-mutated NSCLC and stable, previously treated central nervous system ("CNS") metastases. The initial clinical results from the Phase 2 registration-enabling study (n=112) showed that the ORR was 43%, the disease control rate ("DCR") was 80%, the median duration of response ("mDOR") was 8.5 months (95% confidence interval ("CI"): 6.2 — 13.8), and the mPFS was 6.5 months (95% CI: 4.7 — 8.4). With a January 15, 2022 data cutoff, the median overall survival ("mOS") was 12.6 months (95% CI: 9.2 — 19.2). With respect to CNS-specific activity in a subset analysis of stable, previously treated CNS metastases (n=33), results revealed an intracranial ("IC") ORR of 33% (11/33). Mirati also reported updated findings from a pooled analysis from the KRYSTAL-1 study, including the registrational Phase 2 and Phase 1/1b NSCLC cohorts. The initial results of the pooled analysis of KRYSTAL-1 NSCLC cohorts (n=132) showed that the ORR was 44%, the DCR was 81%, the mDOR was 12.5 months, and the mPFS was 6.9 months. With a January 15, 2022 data cutoff, the mOS was 14.1 months.

In June 2022, Mirati also announced the results of a prospective analysis from the Phase 1b cohort of the KRYSTAL-1 study evaluating IC responses of adagrasib in patients with KRASG12C-mutated advanced NSCLC with active and untreated CNS metastases. The results of the CNS-specific activity in active and untreated CNS metastases (n=19) showed an IC ORR of 32% (6/19).

In addition, the Company treated the first patients in Greater China for the global Phase 3 KRYSTAL-10 study of the combination of adagrasib and cetuximab in patients with KRASG12C-mutated advanced colorectal cancer and for the global Phase 3 KRYSTAL-12 study of adagrasib in patients with KRASG12C-mutated advanced NSCLC in June 2022 and July 2022, respectively.

Bemarituzumab

Our partner Amgen initiated a Phase 1b/2 study (FORTITUDE-301), evaluating the safety and efficacy of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression. In addition, Amgen reported that the final analysis of the FIGHT study, a Phase 2 randomized, double-blind, controlled study evaluating bemarituzumab and modified FOLFOX6 (mFOLFOX6) in patients with previously untreated advanced gastric and gastroesophageal junction cancer was completed, with results continuing to demonstrate that bemarituzumab + mFOLFOX6 improves the clinical outcome of patients with FGFR2b expressing tumors with no new safety concerns and noting that a greater survival benefit was observed with increasing FGFR2b expression levels.

Margetuximab

In January 2022, we announced that the National Medical Products Administration of the People's Republic of China ("**NMPA**") accepted the new drug application (NDA) for margetuximab, an investigational, Fc-engineered monoclonal antibody that targets HER2. The margetuximab NDA is for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease, in combination with chemotherapy.

Repotrectinib

In February 2022, the Center for Drug Evaluation (CDE) of the NMPA granted Breakthrough Therapy Designation for repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have not been treated with a ROS1 TKI. The breakthrough therapy designation was supported by the initial data from both global and Chinese TKI-naïve ROS1-positive NSCLC patients enrolled in the Phase I/II TRIDENT-1 study. We plan to participate in all cohorts of the global TRIDENT-1 study.

In April 2022, we announced topline data for repotrectinib within the China region from the previously disclosed Phase 1/2 TRIDENT-1 study dataset. We plan to discuss topline TKI-naïve data with Chinese health authority in the fourth quarter of 2022.

- In TKI-naïve patients (EXP-1), in 71 total patients, there was a confirmed objective response rate (cORR) of 79% across the global trial. Ten of 11 patients responded within China for a cORR of 91% (95% CI: 59,100) and DOR ranged from 3.6+ to 7.5+ months with a median duration of follow-up of 3.7 months.

- In patients previously treated with 1 TKI and platinum-based chemotherapy (EXP-2), in 26 total patients, there was a cORR of 42% across the global trial. Two of 3 patients responded within China for a cORR of 67% (95% CI:9,99) and DOR ranged from 3.6+ to 3.7+ months with a median duration of follow-up of 3.7 months.

- In patients previously treated with two TKIs without prior chemotherapy (EXP-3), in 18 total patients, there was a cORR of 28% across the global trial. Two of 4 patients responded within China for a cORR of 50% (95% CI: 7,93) and DOR ranged from 1.9+ to 3.4+ months with a median duration of follow-up of 2.6 months.

- In patients previously treated with 1 TKI without prior chemotherapy (EXP-4), in 56 total patients, there was a cORR of 36% across the global trial. Four of 11 patients responded within China for a cORR of 36% (95% CI: 11,69) and DOR ranged from 2.0+ to 3.7+ months with a median duration of follow-up of 3.1 months.

In May 2022, our partner Turning Point Therapeutics, Inc. ("Turning Point") announced that the United States Food and Drug Administration ("FDA") granted an eighth regulatory designation, and third Breakthrough Therapy Designation ("BTD"), to repotrectinib, for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with one ROS1 TKI and who have not received prior platinum-based chemotherapy. In June 2022, the Center for Drug Evaluation ("CDE") of the NMPA granted two Breakthrough Therapy Designations for investigational repotrectinib for the treatment of patients with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and one prior line of platinum-based chemotherapy and for those with ROS1-positive metastatic NSCLC who have received one prior line of ROS1 TKI and no chemotherapy or immunotherapy. The Breakthrough Therapy Designations for repotrectinib were supported by the data from both global and Chinese TKI-pretreated ROS1-positive NSCLC patients enrolled in the Phase 1/2 TRIDENT-1 study.

CLN-081

In June 2022, our partner Cullinan Oncology presented updated data from the Phase 1/2a study in NSCLC patients with EGFR exon 20 insertion mutations at the 2022 ASCO Annual Meeting. Of the 39 patients in the 100 mg BID dose group: 16 (41%) had a confirmed PR; the estimated mDOR was greater than 21 months; mPFS was 12 months; and the safety profile of CLN-081 was amenable for long-term treatment.

BLU-945

In June 2022, we received a Clinical Trial Application approval from the NMPA for the BLU-945 monotherapy cohort of the global Phase 1/2 SYMPHONY study in Greater China.

VYVGART

In June 2022, efgartigimod was introduced to the Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone, and the first Chinese patient was treated with efgartigimod. In July 2022, the NMPA accepted the Biologics License Application for efgartigimod alfa injection for the treatment of adult patients with generalized myasthenia gravis ("gMG") in mainland China.

KarXT

In August 2022, our partner Karuna announced positive topline results from its Phase 3 EMERGENT-2 trial evaluating the efficacy, safety, and tolerability of KarXT in adults with schizophrenia. The trial met its primary endpoint, with KarXT demonstrating a statistically significant and clinically meaningful 9.6-point reduction in the Positive and Negative Syndrome Scale ("PANSS") total score compared to placebo (-21.2 KarXT vs. -11.6 placebo, $p<0.0001$) at Week 5 (Cohen's d effect size of 0.61). KarXT also demonstrated an early and sustained statistically significant reduction of symptoms, as assessed by PANSS total score, starting at Week 2 and maintained such reduction through all timepoints in the trial. The trial also met its key secondary endpoints, demonstrating statistically significant reductions in positive and negative symptoms of schizophrenia, as measured by the PANSS positive, PANSS negative, and PANSS Marder negative subscales. KarXT was generally well tolerated, with a side effect profile substantially consistent with prior trials of KarXT in schizophrenia.

Simurosertib (CDC7 Inhibitor)

Based on an extensive review of the data collected from previously completed studies, we have decided to terminate enrollment for the study of simurosertib.

ZL-1201 (CD47 Inhibitor)

In July 2022, we determined a recommended Phase 2 dose in the ongoing Phase 1 trial. Based on a review of the competitive landscape, Zai Lab has decided to deprioritize ZL-1201 for internal development but will pursue out-licensing opportunities.

Internal Oncology Discovery Portfolio

In April 2022, we presented new data from its internal oncology discovery portfolio at the American Association for Cancer Research (AACR) Annual Meeting 2022. Key early-stage discovery programs were featured in these presentations, including first preview of preclinical data on ZL-1218 (a novel anti-CCR8 antibody for solid tumors) in oral presentation, as well as poster presentations featured ZL-1201 (a CD47-targeting antibody for advanced hematologic malignancies and solid tumors), ZL-1211 (a Claudin18.2-specific antibody for gastric and pancreatic cancer) and ZL-2201 (a highly selective small-molecule DNA-PK inhibitor for anti-cancer therapy).

Recent Business Developments

In March 2022, our shareholders approved a Share Subdivision whereby the Company subdivided each of its issued and unissued ordinary shares into ten ordinary shares, effective March 30, 2022. The one-to-ten Share Subdivision increased the number of our ordinary shares in issue and reduced the nominal value and trading price of each ordinary share. Our Board of Directors believes that the Share Subdivision will increase the trading liquidity of the ordinary shares, lower the investment barrier, and attract more investors to trade in the ordinary shares. In connection with the Share Subdivision, the Company also effected the ADS Ratio Change, whereby the conversion ratio of our ADSs to ordinary shares changed from one ADS to one ordinary share to a new ratio of one ADS representing ten ordinary shares. The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

In March 2022, SEC staff conclusively identified us under the HFCAA as a “Commission-Identified Issuer” because Deloitte Touche Tohmatsu Certified Public Accountants LLP and Deloitte Touche Tohmatsu, our auditor for the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2022, is located in a foreign jurisdiction and the U.S. Public Company Accounting Oversight Board (“PCAOB”) has determined that it is unable to inspect or investigate the auditor completely because of a restriction imposed by a non-U.S. authority in the auditor’s local jurisdiction.

In April 2022, the Audit Committee of our Board of Directors approved the engagement of KPMG LLP ("KPMG"), an auditor located in the United States that is subject to PCAOB inspection, as our independent registered public accounting firm for the fiscal year ending December 31, 2022. In May 2022, we completed our engagement of KPMG to be our independent registered public accounting firm for the fiscal year ending December 31, 2022. On May 25, 2022, the Company received the requisite approvals from the Hong Kong Stock Exchange and the Financial Reporting Council of Hong Kong, and on May 31, 2022, the Company and KPMG signed an engagement letter, and the appointment became effective on the same date. KPMG is engaged to audit our annual consolidated financial statements filed with the SEC and our internal controls over financial reporting in accordance with the Exchange Act, and audit our consolidated financial statements submitted to the Hong Kong Stock Exchange in accordance with the HK Listing Rules.

We also completed our voluntary conversion from secondary listing status to primary listing on the Hong Kong Stock Exchange, effective June 27, 2022 (the "Primary Conversion Effective Date"). The Company's ordinary shares and ADSs will continue to be traded on the Hong Kong Stock Exchange and Nasdaq Global Market ("Nasdaq"), respectively, and remain mutually fungible. Because of our conversion to primary listing in Hong Kong, we are eligible for the Hong Kong Stock Exchange Stock Connect, a channel by which investors in mainland China can invest in stocks traded on the Hong Kong Stock Exchange. Our ordinary shares have been included in the Shenzhen-Hong Kong Stock Connect and Shanghai-Hong Kong Stock Connect programs since June 2022 and July 2022, respectively.

In July 2022, the Board further enhanced our corporate governance by appointing John Diekman to be lead independent director. The Board continues to believe that the Chief Executive Officer is best suited to serve as Chairperson of the Board at this time, including due to her extensive understanding of our business and industry and her ability to identify strategic opportunities, promote the effective execution of strategic initiatives, and facilitate the flow of information between management and the Board. While the roles of Chairperson of the Board and Chief Executive officer are combined, our lead independent director will, among other things, lead meetings of the Board when the Chairperson is not present, serve as liaison between the Chairperson and independent directors, have the authority to call meetings of the independent directors, and, if requested by major shareholders, be available for consultation and direct communication. As a result of Mr. Diekman's appointment as lead independent director, he stepped down as Chair of the Audit Committee, although he will continue to serve as a member of the Audit Committee. As a result, the Board appointed Scott Morrison to be Chair of the Audit Committee.

We also continued to strengthen and expand our leadership team. Joshua Smiley, aged 53, joined the Company as Chief Operating Officer, effective August 1, 2022. Mr. Smiley brings over 26 years of experience working with the biopharmaceutical industry, including experience leading finance, corporate strategy, business development, venture capital, and global business services operations at Eli Lilly and Company. He will report directly to our Chief Executive Officer and will be a key member of our executive committee. He will oversee all aspects of our business, finance, and global operations. In addition, in April 2022, Jonathan Wang became our Chief Business Officer, taking on increased responsibilities after the departure of Tao Fu, our former Chief Strategy Officer.

Recent Legal and Regulatory Developments

Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments)

On April 2, 2022, China Securities Regulatory Commission published the revised Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (the "Draft Archives Rules").

The Draft Archives Rules require that, in relation to the overseas securities offering and listing activities of Chinese domestic enterprises, such domestic enterprises, as well as securities companies and securities service institutions providing relevant securities services, are required to strictly comply with the relevant requirements on confidentiality and archives management, establish a sound confidentiality and archives system and take necessary measures to implement their confidentiality and archives management responsibilities.

According to the Draft Archives Rules, if during the course of an overseas offering and listing (whether listed directly or indirectly), if a Chinese domestic company needs to publicly disclose or provide, or publicly disclose or provide through its overseas listed entity, to relevant entities or individuals including securities companies, other securities service providers and overseas regulators, any documents and materials that contain relevant state secrets, government department work secrets or that have a sensitive impact (i.e., that are detrimental to national security or the public interest if divulged), the Chinese domestic company should complete the relevant approval/filing and other regulatory procedures stipulated by applicable national regulations.

In addition, the Draft Archives Rules explicitly include within the scope of its supervision overseas accounting firms that engage in auditing business related to overseas securities offering and listings of Chinese domestic enterprises. Overseas accounting firms that engage in auditing business related to overseas securities offering and listings of Chinese domestic enterprises are required to abide by corresponding procedures in accordance with relevant Chinese national regulations.

Amended China Civil Procedure Law

The Civil Procedure Law of the People's Republic of China, or the China Civil Procedure Law, which was adopted on April 9, 1991 and amended on October 28, 2007, August 31, 2012, June 27, 2017, and December 24, 2021, prescribes the conditions for instituting a civil action, the jurisdiction of the people's courts, the procedures for conducting a civil action and the procedures for enforcement of a civil judgment or ruling. The most recent amendments to the China Civil Procedure Law on December 24, 2021, which came into effect on January 1, 2022, include the following improvements to the civil procedure under China's current judicial system: (i) with the consent of the parties, civil litigation activities may be conducted online through the information network platform and such online litigation activities have the same legal effect as offline litigation activities; (ii) in addition to civil cases followed by summary procedure, civil cases followed by ordinary procedure and civil cases of second instance which meet certain criteria may also be tried by a single judge; (iii) the scope of the litigation documents which are allowed to be served by electronic means expands to include judgments, awards and mediation statements; (iv) the period of service which is effected by public announcement in cases where the location of the recipient of the service is unknown or the service cannot be served by other means specified in the China Civil Procedure Law is shortened from 60 days to 30 days; (v) with respect to small claims procedure, the amount of the subject matter applicable to small claims procedure is raised, the trial time for small claims procedure is limited to three months and certain types of cases, such as cases of personal relation, are excluded from application of small claims procedure; and (vi) the jurisdiction of judicial conformation of a mediation agreement is further clarified and the parties to a mediation agreement are given more options in terms of choosing the people's court for judicial conformation.

Collecting and Using China-Sourced Human Genetic Resources and Derived Data

On March 4, 2022, the Ministry of Science and Technology (MOST) issued Answers to Frequently Asked Questions Regarding Human Genetic Resources (HGRs) Administration, or the Q&A Series I. The Q&A Series I provides short answers to 30 frequently asked questions relating to the collection, preservation, utilization and external provision of China-sourced HGRs. For example, the Q&A Series I clarifies that a notification filing with the Human Genetic Resources Administration Office of China, or HGRAC, is required for purpose of transferring China-sourced HGRs to regulatory authorities in other jurisdictions.

On March 22, 2022, the Ministry of Science and Technology (MOST) issued the Draft Implementing Rules of the Regulation on the Administration of Human Genetic Resources (Draft for Comment), or the Draft Implementing Rules, which closely scrutinizes all HGRs-related activity from upstream collection of HGR materials to downstream exploitation and external provision of the HGR materials and data derived therefrom ("HGR data"). The Draft Implementing Rules are intended to provide operational details and clarify questions that have emerged in the past few years after the Regulation on the Administration of Human Genetic Resources became effective. Under the Draft Implementing Rules, clinical studies conducted for purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of HGR materials, will be eligible for a notification filing (as opposed to the advance approval) if the HGR materials are collected by sites, and processed by sites or an onshore third-party lab specified in the clinical trial protocol. The Draft Implementing Rules provide clearer guidance on how to allocate the intellectual property derived from a Sino-foreign cooperative research utilizing China-Sourced HGRs. The Draft Implementing Rules enumerate situations where a security review is required for external provision or utilization in an open manner of HGR data, such as external provision or utilization in an open manner of HGR data about important genetic pedigrees, HGR data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals.

On April 15, 2022, MOST issued Answers to Frequently Asked Questions Regarding Human Genetic Resources Administration (Q&A Series II), or the Q&A Series II. The Q&A Series II provide formal written reply to 5 frequently asked questions relating to the collection, preservation, utilization and external provision of China-Sourced HGRs. The Q&A Series II specifies that collection, external provision or utilization in an open manner of the data related to clinical practices, patient demographics, lab tests, medical images, etc. that do not carry genetic attributes will not be regulated as collection, external provision or utilization in an open manner of HGR data. The Q&A Series II stipulates that no advance approval for Sino-foreign cooperative research is required for a research utilizing China-Sourced HGRs, if the foreign entity who provides funding support will not substantially participate in the research and have any access to or ownership of the research data and research results.

Auxiliary Rules for the Regulations on Supervision and Administration of Medical Devices

On March 18, 2021, the State Council published new Regulations on Supervision and Administration of Medical Devices, or Order 739, which became effective on June 1, 2021. This top-level medical device administrative regulation contains a number of important changes, the practical effects of which will be implemented in corresponding auxiliary regulations and rules. Recently, a series of regulations have been amended accordingly to support the implementation of Order 739 in terms of the production, distribution and clinical trials of medical devices.

- Measures for the Supervision and Administration of the Production of Medical Devices

  On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Production of Medical Devices, or Order 53, promulgated by the State Administration for Market Regulation, or SAMR, became effective. All medical device manufacturing activities within China should comply with Order 53. Order 53 clarifies the responsibilities and obligations of medical device registrants/ record-filing applicants and their entrusted manufacturers where applicable. Order 53 also establishes a medical device reporting system with an aim to improve administration of medical device production. The reporting system consists of several types of report, including annual self-inspection report, production product variety report, production conditions change report, re-production report and recall and disposal report. The medical device registrants/record-filing applicants and/or the medical device manufacturers need to submit corresponding reports to the local relevant Medical Product Administrations in accordance with Order 53.

- Measures for the Supervision and Administration of the Distribution of Medical Devices

  On May 1, 2022, a revised version of the Measures for the Supervision and Administration of the Distribution of Medical Devices, or Order 54, promulgated by SAMR came into effect. All medical device distribution activities within China should comply with Order 54. Under Order 54, explicit regulatory requirements were introduced to distributors of medical devices. For example, Order 54 requires medical device distributors to establish quality management system and adopt quality control measures covering the total process of distribution and submit annual self-inspection reports to local relevant Medical Product Administrations.

- Good Practices for Medical Device Clinical Trials

  On May 1, 2022, a revised version of the Good Practices for Medical Device Clinical Trials, or 2022 Medical Device GCP, jointly released by the NMPA and the National Health Commission, came into effect. Going forward, all medical device clinical trials that haven't passed ethical review by May 1, 2022 should be conducted in compliance with the 2022 Medical Device GCP, if they are conducted for purpose of applying for medical device registration. The 2022 Medical Device GCP specifies responsibilities of each party participating in a medical device clinical trial, in particular the responsibilities of the sponsor. The 2022 Medical Device GCP no longer requires clinical trials of medical devices to be conducted in two or more clinical trial institutions. This will make it easier for medical device companies to conduct medical device registration studies.

Amendment to the Implementation Regulation of the Drug Administration Law of the People's Republic of China (the "PRC")

On May 9, 2022, the NMPA published a comprehensive draft of Amendment to the Implementation Regulation of the PRC Drug Administration Law (the "Draft DAL Implementing Regulations") for public comments. The Draft DAL Implementing Regulations introduced changes to the regulatory framework and aimed to codify certain regulatory initiatives implemented by the Chinese government since the promulgation of the current PRC Drug Administration Law in 2019 (the "DAL").

The Draft DAL Implementing Regulations propose to extend the reach of DAL to offshore development and manufacturing activities of pharmaceutical companies to the extent that the pharmaceutical companies would like to obtain marketing authorizations for their drug products in mainland China. All overseas R&D activities and production activities concerning a drug to be marketed in mainland China and/or already marketed in mainland China should be carried out in compliance with the regulatory requirements specified in applicable Chinese laws, regulations, rules, standards, and specifications.

Patent linkage and regulatory data protection have been included in the Draft DAL Implementing Regulations. The Draft DAL Implementing Regulations propose to grant market exclusivity with a specified period to first-to-market generic drug contributing to the invalidity of relevant drug patent.

PRC Anti-Monopoly Law

On June 24, 2022, the Standing Committee of the National People's Congress published amendments to the PRC Anti-Monopoly Law (the "AML"), which came into effect on August 1, 2022. The amended AML formally implements China's latest anti-monopoly policies by, among other things, improving regulatory rules for anti-competitive agreements, expressly addressing monopoly issues in the platform economy, and substantially increasing the penalties for violating the law.

The improvements of the regulatory rules for anti-competitive agreements made by the amended AML mainly includes: (i) expressly stipulating that an agreement which fixes or limits resale prices, that is, a vertical anti-competitive agreement, is not prohibited if relevant business operators can prove that such agreement does not have the effect of eliminating or restricting competition; (ii) formally provides the "safe harbor" regime which stipulates that a vertical anti-competitive agreement is not prohibited, if the parties' market share in the relevant market is lower than the market share percentage set by the anti-monopoly enforcement agency and other conditions established by the anti-monopoly enforcement agency are met; (iii) codifies that business operators shall not organize other business operators to reach a monopoly agreement or provide substantial assistance for other business operators to reach a monopoly agreement.

The amended AML formally extends the anti-monopoly regulatory regime to the platform economy by outlining the general principal that business operators shall not engage in monopolistic activities, such as by taking advantage of data and algorithms, technology, capital advantage, and platform rules. The amended AML also specifically prohibits business operators from abusing market dominance, such as by using data and algorithms, technology, and platform rules.

Penalties for violation of the AML have been substantially increased by the amended AML. For example, according to the amended AML, if a company completes a concentration of business in violation of the AML that will have or is likely to have the effect of eliminating or restricting competition, in addition to other remedial measures, a fine of up to 10% of the last year's sales revenue may be imposed. If the concentration of business in violation of the AML completed by the company does not have the effect of eliminating or restricting competition, a fine of up to RMB5 million may be imposed. In the case that the aforementioned violation has particularly serious circumstances, bad impact, or consequences, the fine imposed may be further increased to between two and five times the aforementioned fine amount.

Cross-Border Data Transfers

Measures on Security Assessment of Cross-Border Data Transfer

On July 7, 2022, the Cyberspace Administration of China ("CAC") issued the Measures on Security Assessment of Cross-Border Data Transfer (the "Security Assessment Measures"), which set out a security assessment framework for cross-border data transfers out of mainland China as well as ground rules for a security assessment filing for cross-border data transfers which was stipulated in the PRC Cybersecurity Law ("CSL") and the PRC Personal Information Protection Law ("PIPL").

A security assessment will be triggered if a cross-border data transfer out of mainland China falls into any of the following scenarios: (i) transfer of important data by data processors; (ii) transfer of personal information ("PI") by critical information infrastructure operators ("CIIOs") and data processors that process PI of more than one million individuals; (iii) transfer of PI by data processors that have transferred either PI of over 100,000 individuals or sensitive PI of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. According to statements by the CAC, a cross-border data transfer includes (i) an outbound transfer and overseas storage of data collected and generated during a data processor's operation in mainland China; and (ii) a remote access or use of data collected and generated by a data processor stored within mainland China by overseas institutions, organizations, and individuals.

Prior to applying for a security assessment with the CAC, data processors are required to carry out a self-risk assessment, which needs to be presented to the CAC along with an application filing and other required materials for a security assessment. During a security assessment, the CAC will primarily focus on risks to national security, public interests, and the legitimate rights and interests of individuals or organizations that such cross-border data transfer may cause. A cross-border data transfer of relevant data will not be allowed if the CAC does not approve the security assessment filing. Once the CAC approves the security assessment filing, such approval will remain valid for two years and may be renewed. An application for security assessment needs to be re-submitted if there is a change in the cross-border data transfer that may affect the security of the exported data, such as changes in the purpose, method, scope, and type of the exported data and changes in the purpose and method of the processing of the exported data by overseas recipients.

The Security Assessment Measures have retroactive effect for cross-border data transfers out of mainland China of relevant data conducted prior to their effective date on September 1, 2022. If a data processor fails to complete its security assessment for any of its cross-border data transfers of relevant data out of mainland China prior to the effective date of the Security Assessment Measures, it needs to rectify the failure within six months after the effective date of the Security Assessment Measures.

Specification for Certification of Personal Information Cross-Border Processing Activities

On June 24, 2022, the National Information Security Standardization Technical Committee issued Guidance on Network Security Standardized Practice — Specification for Certification of Personal Information Cross-Border Processing Activities (the "Certification Specification"), which serves as an industry standard. The Certification Specification provides that PI processors may apply for a personal information protection certification (a "PIPC") from certain qualified institutions, pursuant

to which PI processors, provided that the requirements stipulated by PIPL are met, may rely on a PIPC to comply with cross-border PI transfer requirements when engaging in (i) intra-group cross-border transfers within a multinational company or subsidiaries or affiliated companies of an economic/business entity, or (ii) data processing activities conducted outside of mainland China involving PI of individuals located in mainland China subject to the extra-territorial jurisdiction of the PIPL.

The PI processors involved in PI cross-border activities shall carry out a prior self-risk assessment focusing on whether the cross-border PI transfer is legitimate, justifiable, and necessary and the security protection measures taken are effective and appropriate to the degree of risks. A self-risk assessment must include the following factors: (i) whether the cross-border PI transfer complies with applicable laws and administrative regulations; (ii) the impact on the rights and interests of PI subjects, particularly the impact of the legal environment and network security environment of the foreign countries and regions; and (iii) other matters necessary to safeguard the rights and interests in relation to PI.

The list of qualified institutions for PIPC has not been released to date, and therefore, it is not yet possible for companies to rely on a PIPC to legitimize their cross-border data transfers.

Standard Contract for Cross-Border PI Transfer and Accompanying Regulations

On June 30, 2022, the CAC issued for public consultation draft Regulations on the Standard Contract for Cross-Border Transfer of Personal Information, which introduced a draft standard contract for the cross-border transfer of PI outside of mainland China (the "PRC SC"). The PRC SC clarifies terms and conditions to be agreed on between PI processors as a data exporter and an overseas recipient as a data importer with respect to cross-border data transfers of PI out of mainland China. When finalized, the PRC SC can be used to comply with requirements under the PIPL for cross-border data transfers of PI out of mainland China that do not need to undergo a security assessment.

When finalized, a PI processor may enter into the PRC SC and provide it along with other required materials to relevant governmental authorities for filing to ensure the legality of a cross-border transfer out of mainland China if the following conditions are satisfied: the PI processor (i) is not a CIIO; (ii) processes PI of fewer than 1 million individuals; (iii) has provided PI of fewer than 100,000 individuals overseas in aggregate since January 1 of the preceding year; and (iv) has provided sensitive PI of fewer than 10,000 individuals overseas in aggregate since January 1 of the preceding year.

The PRC SC imposes certain obligations on the parties of such cross-border PI transfers to protect the interests of PI subjects, including, for example, (i) data exporters are required to use reasonable efforts to ensure data importers have adequate technical and organizational measures to ensure secure processing and have relevant capabilities to fulfill their obligations relating to the data transfer, and (ii) the parties of such cross-border transfer are required to ensure that the rights and interests of data subjects are well recognized in practice (and data subjects' inquiries are promptly responded to), as such data subjects are considered third-party beneficiaries of the PRC SC.

Factors Affecting Our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of product candidates has been advancing and expanding, with twelve late-stage clinical product candidates being investigated as of June 30, 2022.

We have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, multiple follow-on offerings, and a secondary listing on the Hong Kong Stock Exchange in September 2020. Through June 30, 2022, we have raised approximately $164.6 million from private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, follow-on offerings, and secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $132.0 million and $235.3 million for the six months ended June 30, 2022 and 2021, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our twelve late-stage clinical product candidates, research and develop our clinical- and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. We review such expenditures for prioritization and efficiency purposes. These expenditures include:

- expenses incurred for contract research organizations (CROs), contract manufacture organizations (CMOs), investigators and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expenses;
- expenses for licensors;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations;
- expenses associated with the construction and maintenance of our manufacturing facilities; and
- costs associated with operating as a public company.

The Company is in the process of evaluating its development programs and is developing a series of recommendations for prioritizing these programs to concentrate our resources on programs that have the greatest potential to beneficially impact patients, strengthen our global competitiveness, and provide long-term sustainability.

Selling, General, and Administrative Expenses

Our selling, general, and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general, and administrative expenses include product distribution and promotion costs, professional service fees for legal, intellectual property, consulting, auditing, and tax services

as well as other direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies used in selling, general, and administrative activities. We anticipate that our selling, general, and administrative expenses will increase in future periods to support increases in our commercial and research and development activities and as we continue to commercialize, develop, and manufacture our products and assets. These increases will likely include increased headcount, increased share-based compensation charges, increased product distribution and promotion costs, expanded infrastructure, and increased costs for insurance. We also anticipate incurring additional legal, compliance, accounting, and investor and public relations expenses associated with being a public company.

Our Ability to Commercialize Our Product Candidates

As of June 30, 2022, twelve of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may never occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones for the relevant products under these agreements as well as tiered royalties based on the net sales of the licensed products. These accruals for upfront and milestone payments are recorded in research and development expense and were $10.4 million for the six months ended June 30, 2022 and $269.2 million for the six months ended June 30, 2021, respectively.

COVID-19 Impact and Related Risks

Our business operations and those of our suppliers, CROs, CMOs, and other contractors and third parties on which we rely — as well as the Chinese economy more broadly — have been, and may continue to be, adversely affected by the effects of the COVID-19 pandemic and such government measures taken in response.

The effects of the COVID-19 pandemic and restrictive quarantine measures imposed by the Chinese government in response, especially between March and May 2022, have adversely affected our business, and may continue to adversely affect our business, perhaps significantly, for the remainder of this fiscal year and beyond, depending on the nature, severity, and duration of the ongoing effects of the COVID-19 pandemic, particularly in mainland China where our operations are primarily located.

Specifically, the COVID-19 pandemic has adversely impacted our operations, business, and financial results, including our manufacturing and supply chain, our and our partners' sales, marketing, and clinical trial operations, and our ability to advance our research and development

activities and pursue the development of our pipeline products. We expect some residual revenue impacts from the lockdown measures in mainland China from March 2022 to May 2022 to be reflected in our results for the second half of 2022. Although so far none of our NDA submissions and acceptances, key clinical development milestones, or clinical trial application approvals have been materially delayed, there is no guarantee this will continue to be the case.

Additionally, the COVID-19 government restrictions and shutdown orders — those currently in effect and those which may be imposed in the future — may cause us or our commercial partners, licensors, and CMOs to experience delays or interruptions in the ability to manufacture and supply the products we are selling commercially in Greater China. These and other government restrictions may limit our and our distributors' ability to successfully sell our commercial products in Greater China, even if we implement contingency plans. Any or all of these adverse effects arising from COVID-19 may adversely affect our business and results of operations this year, and perhaps beyond, or cause the value of the Company to decline, potentially limiting our ability to obtain additional financing on terms acceptable to the Company.

COVID-19 government restrictions and lockdown orders, including those requiring our employees to work from their homes or preventing our executives from traveling to or from mainland China, Hong Kong, and the United States, could also negatively affect our business, such as through absenteeism or employee turnover, other operational disruptions, or increased risk of a cybersecurity incident.

There are no comparable recent events that provide guidance as to the effect the COVID-19 outbreak as a global pandemic may have and, as a result, the ultimate impact of the pandemic is highly uncertain and subject to change, and the actual effects on our business and results of operations will depend on many factors beyond our control.

FUTURE AND OUTLOOK

Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing, and commercializing our portfolio to positively impact human health worldwide. For the remainder of the year, our corporate priorities include the following:

1. We seek to accelerate important data readouts and regulatory filings across our entire portfolio. For example, we plan to discuss the regulatory pathway for Repotrectinib with the NMPA at a pre-NDA meeting in the fourth quarter of 2022. We also plan to initiate a pivotal study for CLN-081 following the completion of a pharmacokinetic food effect study in 2022. With respect to Sulbactam-Durlobactam (SUL-DUR), submission of an NDA to the FDA is expected in the third quarter of 2022, and we expect to submit an NDA to the NMPA in the fourth quarter of 2022.

2. Continue to invest in R&D and advance our internal pipeline with global rights. Specifically, we plan to advance ZL-1102 (anti-IL-17A Humabody®) into full global development and anticipate to initiate a global Phase 2 study for chronic plaque psoriasis (CPP) in the fourth quarter of 2022.

3. Leverage our position in China to continue increasing our revenue base and to source innovation internally and externally with potentially transformative assets and partnership opportunities.

FINANCIAL REVIEW

Results of Operations

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		Change	
	2022	2021	**$**	**%**
Revenues:				
Product revenue, net	**93,670**	57,038	36,632	64%
Collaboration revenue	**1,230**	—	1,230	100%
Total revenues	**94,900**	57,038	37,862	66%
Expenses:				
Cost of sales	**(33,051)**	(18,373)	(14,678)	80%
Research and development	**(119,938)**	(346,076)	226,138	(65)%
Selling, general, and administrative	**(120,392)**	(90,252)	(30,140)	33%
Loss from operations	**(178,481)**	(397,663)	219,182	(55)%
Interest income	**1,363**	458	905	198%
Other income (expenses), net	**(42,988)**	1,179	(44,167)	(3,746)%
Loss before income tax and share of loss from equity method investment	**(220,106)**	(396,026)	175,920	(44)%
Income tax expense	**—**	—	—	—%
Share of loss from equity method investment	**(221)**	(208)	(13)	6%
Net loss	**(220,327)**	(396,234)	175,907	(44)%
Net loss attributable to ordinary shareholders	**(220,327)**	(396,234)	175,907	(44)%

Revenues

Product Revenue, net

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. Sales rebates are offered to distributors in mainland China and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories.

The Company lowered the selling price of ZEJULA due to its inclusion in the NRDL for certain therapies. Accordingly, the Company accrued $2.9 million of sales rebates as compensation to distributors for those products previously sold at the price prior to the NRDL implementation during the six months ended June 30, 2022, and $22.0 million during the six months ended June 30, 2021.

QINLOCK and NUZYRA are also scheduled to enter negotiations with the National Healthcare Security Administration regarding potential inclusion in the NRDL, and in June 2022, the Company lowered the selling price for these products. Accordingly, the Company accrued $2.7 million and $0.2 million for sales rebates as compensation to distributors previously sold at the price prior to the reduction during the six months ended June 30, 2022 for QINLOCK and NUZYRA, respectively.

In addition, between March 2022 and May 2022, a number of government restrictions or lockdown measures were imposed in Greater China to help control the spread of COVID-19, including in some large cities like Shanghai. These government restrictions or lockdown measures caused some patients to have limited or no access to ZEJULA, Optune, QINLOCK, or NUZYRA, which had a negative impact on our revenue. Although the revenue impact was modest in the second quarter of 2022, we expect some residual revenue impacts in the second half of 2022. For more information on risks related to the COVID-19 pandemic, see "COVID-19 Impact and Related Risks" below.

The following table presents net revenue by product for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		**Change**	
	2022	2021	**$**	**%**
ZEJULA	**63,649**	35,972	27,677	77%
Optune	**24,389**	16,665	7,724	46%
QINLOCK	**3,582**	4,401	(819)	(19)%
NUZYRA	**2,050**	—	2,050	—%
Total product revenue, net	**93,670**	57,038	36,632	64%

Collaboration revenue

Collaboration revenue increased by $1.2 million for the six months ended June 30, 2022 from nil for the six months ended June 30, 2021. These increases were due to our collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

Cost of Sales

Cost of sales increased by $14.7 million to $33.1 million for the six months ended June 30, 2022 from $18.4 million for the six months ended June 30, 2021. These increases were primarily due to increasing sales volume, higher product costs, and higher royalties.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		**Change**	
	2022	2021	**$**	**%**
Research and development expenses:				
Personnel compensation and related costs	**$ 51,847**	$ 29,979	$ 21,868	73%
Licensing fees	**10,436**	269,248	(258,812)	(96)%
CROs/CMOs/Investigators expenses	**46,918**	35,144	11,774	34%
Other costs	**10,737**	11,705	(968)	(8)%
Total	**$119,938**	$346,076	$(226,138)	(65)%

Research and development expenses decreased by $226.1 million to $119.9 million for the six months ended June 30, 2022 from $346.1 million for the six months ended June 30, 2021 primarily due to:

- a decrease of $258.8 million in licensing fees as we recorded no upfront payments for licensing agreements; partially offset by

- an increase of $21.9 million in personnel compensation and related costs primarily attributable to increased employee compensation costs due to headcount growth and the grants of new share options and restricted shares and the continued vesting of those awards during the six months ended June 30, 2022;

- an increase of $11.8 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials in the six months ended June 30, 2022.

The following table summarizes our research and development expenses by program for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		Change	
	2022	2021	**$**	**%**
Research and development expenses:				
Clinical programs	**$ 56,444**	$279,689	$(223,245)	(80)%
Pre-clinical programs	**4,222**	31,045	(26,823)	(86)%
Unallocated research and development expenses	**59,272**	35,342	23,930	68%
Total	**$119,938**	$346,076	$(226,138)	(65)%

Research and development expenses attributable to clinical programs decreased by $223.2 million to $56.4 million for the six months ended June 30, 2022 from $279.7 million during the six months ended June 30, 2021. Research and development expenses attributable to pre-clinical programs decreased by $26.8 million to $4.2 million for the six months ended June 30, 2022 from $31.0 million during the six months ended June 30, 2021. Those decreases were driven by decreased license fees.

Although we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any given time.

Selling, General, and Administrative Expenses

The following table summarizes our selling, general and administrative expenses by program for the six months ended June 30, 2022 and 2021 (in thousands, except percentages):

	Six Months Ended June 30,		Change	
	2022	2021	**$**	**%**
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	**$ 79,523**	$53,472	$26,051	49%
Professional service fees	**15,505**	8,389	7,116	85%
Other costs	**25,364**	28,391	(3,027)	(11)%
Total	**$120,392**	$90,252	$30,140	33%

Selling, general, and administrative expenses increased by $30.1 million to $120.4 million for the six months ended June 30, 2022 from $90.3 million for the six months ended June 30, 2021 primarily due to:

- an increase of $26.1 million in personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs due to headcount growth and grants of new share options and restricted shares and the continued vesting of those awards during the six months ended June 30, 2022;

- an increase of $7.1 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; those increases were partially offset by

- a decrease of $3.0 million in other costs mainly related to selling, rental, and administrative expenses primarily for the commercial operation in mainland China, Hong Kong, and Taiwan.

Interest Income

Interest income was $1.4 million and $0.5 million for the six months ended June 30, 2022 and 2021, respectively.

Other Income (Expenses), Net

Other income (expenses), net decreased by $44.2 million to $43.0 million of net expense for the six months ended June 30, 2022 from $1.2 million of net income for the six months ended June 30, 2021 primarily as a result of an increase in foreign exchange loss of $33.5 million and an equity investment loss in MacroGenics of $12.6 million, partially offset by an increase in governmental subsidies of $1.5 million.

Discussion of Certain Key Balance Sheet Items

Cash, cash equivalents, restricted cash and short-term investments

As of June 30, 2022, the Company's cash, cash equivalents, restricted cash and short-term investments primarily comprised of (1) approximately $1,187.6 million denominated in US dollars; (2)approximately RMB425.2 million (equivalent to approximately $63.4 million) denominated in Renminbi; and (3) approximately $5.9 million denominated in Hong Kong dollar, Australian dollar, and Taiwan dollar.

Accounts receivable

Accounts receivable decreased by 43.0% from $47.5 million as of December 31, 2021 to $27.1 million as of June 30, 2022, primarily due to the collection of receivable from Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.("Hanhui") of RMB70.0 million (USD$11.0 million) for the upfront payment and the acceleration of the collection of receivables from our customers for the six months ended June 30, 2022.

Inventories

The inventories increased by 23.2% from $19.0 million as of December 31, 2021 to $23.3 million as of June 30, 2022, mainly because we built up the inventory balance in anticipation of increasing sales in mainland China.

Property and equipment, net

The property and equipment increased by 7.7% from $43.1 million as of December 31, 2021 to $46.4 million as of June 30, 2022, primarily attribute to our on-going buildout of the Suzhou manufacturing facility, expansion of business development and research and development activities.

Accounts payable

Accounts payable includes amounts due to third parties and totaled $108.4 million and $126.2 million as of June 30, 2022 and December 31, 2021, respectively.

The following table sets forth an aging analysis of accounts payable as of the dates indicated, which is based on invoice date (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Within 3 months	**107,498**	125,709
3 months to 6 months	**731**	416
6 months to 1 year	**199**	22
Over 1 year	**15**	16
Total	**108,443**	126,163

Other current liabilities

The following table presents the Company's other current liabilities as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Payroll	**18,976**	25,685
Accrued rebate to distributors	**11,249**	15,001
Tax payables	**9,896**	8,817
Accrued professional service fee	**6,450**	4,319
Other	**5,827**	4,421
Payables for purchase of property and equipment	**1,212**	2,568
Total	**53,610**	60,811

Other current liabilities decreased by 11.8% from $60.8 million as of December 31, 2021 to $53.6 million as of June 30, 2022. The decrease was primarily due to payment of bonus.

Liquidity and Capital Resources

The following table represents our cash and cash equivalents and short-term investments as of June 30, 2022 and December 31, 2021 (in thousands):

	June 30, 2022	December 31, 2021
	$	$
Cash and cash equivalents	**680,820**	964,100
Short-term investments	**575,274**	445,000

We have financed our activities primarily through private placements, our September 2017 initial public offering on Nasdaq, various follow-on offerings, and our September 2020 secondary listing on the Hong Kong Stock Exchange of our ordinary shares and/or ADSs. Through June 30, 2022, we have raised approximately $164.6 million from private equity financing and approximately $2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, secondary listing, and subsequent follow-on offerings.

Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $132.0 million and $235.3 million for the six months ended June 30, 2022 and 2021, respectively. We have commitments for capital expenditure of $19.5 million as of June 30, 2022, mainly for the purpose of plant construction and installation. We currently are not aware of any events that are reasonably likely to cause a material change in the relationship between our costs and revenues.

As of June 30, 2022, we had cash, cash equivalents, restricted cash, and short-term investments of $1,256.9 million. Our expenditures are principally focused on research and development and are largely discretionary. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash, and short-term investments will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. However, in order to bring to fruition our research and development objectives, we will ultimately need additional funding sources, and there can be no assurances that they will be made available.

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		**Change**
	2022	2021	**$**
Net cash used in operating activities	**$(132,027)**	$ (235,348)	$ 103,321
Net cash (used in) provided by investing activities	**(143,869)**	737,828	(881,697)
Net cash (used in) provided by financing activities	**(2,240)**	820,949	(823,189)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	**(5,144)**	1,028	(6,172)
Net (decrease) increase in cash, cash equivalents and restricted cash	**$(283,280)**	$1,324,457	$(1,607,737)

Net Cash Used in Operating Activities

During the six months ended June 30, 2022, our operating activities used $132.0 million of cash, which resulted principally from our net loss of $220.3 million, adjusted for non-cash charges of $45.9 million, and cash used in our operating assets and liabilities of $42.4 million.

During the six months ended June 30, 2021, our operating activities used $235.3 million of cash, which resulted principally from our net loss of $396.2 million, adjusted for non-cash charges of $85.9 million, and cash provided in our operating assets and liabilities of $75.0 million.

Net cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $143.9 million for the six months ended June 30, 2022 compared to net cash provided by investing activities of $737.8 million for the six months ended June 30, 2021. The shift from cash provided by to cash used in investing activities was primarily due to a decrease of $613.9 million in proceeds from the maturity of short-term investments, an increase of $260.3 million in purchases of short-term investments, and an increase of $7.8 million from purchases of property and equipment during the six months ended June 30, 2022 compared to the six months ended June 30, 2021.

Financing Activities

Net cash used by financing activities was $2.2 million for the six months ended June 30, 2022 compared to net cash provided by financing activities of $820.9 million for the six months ended June 30, 2021. The shift from cash provided by to cash used in financing activities was primarily because we had proceeds of $818.9 million from our issuance of ordinary shares upon public offerings during the six months ended June 30, 2021 while there were no such transactions during the six months ended June 30, 2022.

Effect of Exchange Rates on Cash

We have substantial operations in mainland China, which generate a significant amount of RMB-denominated cash from product sales and require a significant amount of RMB-denominated cash to pay our obligations. Since the reporting currency of the Company is the U.S. dollar, periods of volatility in exchange rates may have a significant impact on our consolidated cash balances.

Operating Capital Requirements

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue to commercialize our approved products, continue our research and development efforts related to our clinical and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek and/or expand regulatory approval for, ZEJULA, Optune, QINLOCK, NUZYRA, and our other products and product candidates. In addition, if we obtain regulatory approval for any additional product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. In particular, if more of our product candidates are approved, additional costs may be substantial as we may have to, among other things, modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers and increase our commercial workforce. We have incurred, and may continue to incur, expenses as we create additional infrastructure to support our operations. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure that we will have sufficient cash from other sources to fund our operations. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements, or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce, or terminate our research and development programs or any future commercialization efforts.

Our future capital requirements will depend on many factors, including:

- the cost and timing of future commercialization activities for ZEJULA, Optune, QINLOCK, NUZYRA, and any other product candidates for which we receive regulatory approval;
- the pricing of and product revenues received, if any, from future commercial sales of our approved products and any other products for which we receive regulatory approval;
- the scope, progress, timing, results, and costs of clinical development of our products in additional indications, if any;

- the scope, progress, timing, results, and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the cost, timing, and outcome of seeking, obtaining, maintaining, and expanding regulatory approval of our products and product candidates;
- our ability to establish and maintain strategic partnerships, collaboration, licensing, or other arrangements and the economic and other terms, timing, and success of such arrangements;
- the cost, timing, and outcome of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property related claims;
- the extent to which we acquire or in-license other product candidates and technologies and the economic and other terms, timing, and success of such collaboration and licensing arrangements;
- cash requirements of any future acquisitions;
- the number, characteristics, and development requirements of the product candidates we pursue;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- our headcount growth and associated costs; and
- the costs of operating as a public company in both the United States and Hong Kong.

Contractual Obligations and Commitments

As of June 30, 2022, purchase commitments amounted to $19.5 million, which is related to purchase of property and equipment contracted and expected to be incurred within one year. We do not have any other purchase commitments beyond one year.

Credit Risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, short-term investments, accounts receivable, and notes receivable.

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $680.8 million and $964.1 million and short-term investments of $575.3 million and $445.0 million as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and we continually monitor the credit worthiness of these financial institutions.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangements. We manage credit risk of accounts receivable through ongoing monitoring of the outstanding balances and limit the amount of credit extended based upon payment history and the debtor's current credit worthiness. Historically, we have collected the receivables from customers within the credit terms with no significant credit losses incurred. As of June 30, 2022, our two largest debtors collectively accounted for approximately 35% of our total accounts receivable.

Certain accounts receivable balances are settled in the form of notes receivable. As of June 30, 2022, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

Foreign Currency Exchange Rate Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Company included aggregated amounts of RMB425.2 million and RMB151.7 million, which were denominated in RMB, representing 9% and 2% of the cash and cash equivalents, as of June 30, 2022 and December 31, 2021, respectively.

Our business mainly operates in mainland China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have significant direct foreign exchange risk and have not used derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMB, while ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in Greater China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, the Chinese government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that Chinese government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, in August 2015, the PBOC significantly devalued the RMB.

The value of our ADSs and our ordinary shares will be affected by the foreign exchange rates between U.S. dollars, HK dollars and the RMB. For example, to the extent that we need to convert U.S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or the HK dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars or HK 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 or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us.

Since 1983, the Hong Kong Monetary Authority ("HKMA") has pegged the HK dollar to the U.S. dollar at the rate of approximately HK$7.80 to US$1.00. However, there is no assurance that the HK dollar will continue to be pegged to the U.S. dollar or that the HK dollar conversion rate will remain at HK$7.80 to US$1.00. If the HK dollar conversion rate against the U.S. dollar changes and the value of the HK dollar depreciates against the U.S. dollar, our assets denominated in HK dollars will be adversely affected. Additionally, if the HKMA were to repeg the HK dollar to, for example, the RMB rather than the U.S. dollar, or otherwise restrict the conversion of HK dollars into other currencies, then our assets denominated in HK dollars will be adversely affected.

Inflation

In recent years, mainland China has not experienced significant inflation and thus inflation has not had a material impact on our results of operations. However, the global economy, including the U.S. economy, has experienced rising inflation in recent quarters. 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.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under the rules of the SEC, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Gearing Ratio

The gearing ratio of the Company, which was calculated by dividing total interest-bearing loans by total shareholders' equity as of the end of the period, were both nil as of June 30, 2022 and December 31, 2021 because we do not have any interest-bearing loans.

Significant Investments Held

Except as disclosed in Note 2 of the unaudited interim condensed consolidated financial statements as of June 30, 2022, we did not hold any other significant investments as of June 30, 2022 and December 31, 2021.

Future Plans for Material Investments and Capital Assets

We do not have any future plans for material investments or capital assets as of June 30, 2022.

Material Acquisitions and Disposals of Subsidiaries and Affiliated Companies

During the six months ended June 30, 2022, we did not have any material acquisitions and disposals of subsidiaries and affiliated companies.

Employee and Remuneration Policy

As of June 30, 2022, we had a global team of 2,063 full-time employees, which increased from 1,951 full-time employees as of January 31, 2022.

The remuneration policy and package of our employees are periodically reviewed by the Compensation Committee of the Board. The packages were set by benchmarking with companies in similar industries and companies with similar complexity and size. In addition to cash compensation and benefits, we may issue share options, share appreciation rights, restricted shares, unrestricted shares, share units including restricted share units, performance awards, and other types of awards to our employees in accordance with our equity incentive plans. We also provide comprehensive training programs to our employees to meet their various development needs, including leadership development programs, upskills programs and on-the-job trainings, etc. The total remuneration cost incurred by the Company for the six months ended June 30, 2022 was $129.5 million (June 30, 2021: $80.9 million).

Pledge of Assets

As of June 30, 2022 and December 31, 2021, we did not have any pledge of assets.

Contingent Liabilities

As of June 30, 2022 and December 31, 2021, we did not have any material contingent liabilities. See Note 14 of the unaudited interim condensed consolidated financial statements as of June 30, 2022 for contractual obligations under licenses and collaborative agreements.

Interim Dividend

The Board did not recommend any interim dividend for the six months ended June 30, 2022 and 2021, respectively.

Recent Accounting Pronouncements

See Note 2 to the unaudited interim condensed consolidated financial statements included in this announcement regarding recent accounting pronouncements.

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company's corporate governance practices are based on the principles and code provisions set forth in the Corporate Governance Code (the "CG Code") contained in Appendix 14 to the HK Listing Rules.

Pursuant to code provision C.2.1 of the CG Code, companies listed on the Hong Kong Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities of the Chairperson and the Chief Executive Officer should be segregated and should not be performed by the same individual. Dr. Samantha Du currently serves as our Chairperson and Chief Executive Officer. The Board believes that Dr. Samantha Du is the director best suited to serve as Chairperson, including due to her extensive understanding of our business and industry and her ability to identify strategic opportunities, promote the effective execution of strategic initiatives, and facilitate the flow of information between management and the Board. The Board believes that the balance of power and authority on the Board will not be impaired due to this arrangement. The Board will review the corporate governance structure and practices from time to time and shall make changes the Board considers appropriate.

Except as disclosed above, from the Primary Conversion Effective Date to the date of this announcement, the Company has complied with the provisions set out in the CG Code.

The Board will continue to periodically review and monitor its corporate governance practices for compliance with the CG Code and maintain a high standard of corporate governance practices of the Company.

Compliance with Policies Equivalent to the Model Code for Securities Transactions by Directors of Listed Issuers

The Company has adopted its own insider dealing policies on terms no less exacting than those in the Model Code for Securities Transactions as set forth in Appendix 10 to the HK Listing Rules (the "Model Code") regarding directors' dealings in the securities of the Company.

Having made specific enquiry of all the Directors, all the Directors confirmed that they have complied with the required standards set forth in the Company's insider dealing policies throughout the period from the Primary Conversion Effective Date to June 30, 2022.

Purchase, Sale or Redemption of the Company's Listed Securities

During the Reporting Period, the Company did not purchase, sell, or redeem any of the Company's securities listed on the Hong Kong Stock Exchange.

Disclosure of Changes in Directors' Information Pursuant to Rule 13.51(B)(1) of the HK Listing Rules

Upon specific enquiry by the Company and following confirmations from directors, except as disclosed hereunder, there is no change in the information of directors required to be disclosed pursuant to Rule 13.51(B)(1) of the HK Listing Rules during the Reporting Period. The change of directors' information is set forth below.

Ms. Nisa Leung resigned as a non-executive director and a member of the audit committee of the board of directors of New Horizon Health Limited (Stock Code: 6606) with effect from February 28, 2022 due to other business commitments. Ms. Leung has also served as an independent non-executive director, a member of the audit committee and a member of risk committee of Hong Kong Exchanges and Clearing Limited (Stock Code: 0388) since April 28, 2021.

The Compensation Committee of the Board actively reviews and assesses the executive compensation program in light of the highly competitive employment environment and the challenge of recruiting, motivating and retaining executives. Please refer to the definitive proxy statement/circular for 2022 Annual General Meeting dated May 3, 2022 for the compensation program of Dr. Du and the compensation policy of independent non-employee directors.

USE OF NET PROCEEDS

Use of Net Proceeds from April 2021 Offering

In April 2021, the Company issued 224,000 ordinary shares of the Company at a price of HK$1,164.20 per share and 5,492,400 ADSs at a price of US$150.00 per ADS for aggregate cash consideration (before deducting underwriting discounts and commissions and other offering expenses) of approximately $857.5 million.

As of the date of this announcement, there has been no change in the intended use of net proceeds raised from this offering, which amounted to approximately $818.0 million, as disclosed in the announcement of the Company dated April 21, 2021:

- approximately 30% of the net proceeds to fund new business and corporate development and licensing opportunities;
- approximately 30% of the net proceeds to complete clinical trials and advance new drug candidates;
- approximately 20% of the net proceeds to expand the Company's commercialization efforts;
- approximately 15% of the net proceeds to enhance the Company's global pipeline; and
- approximately 5% of the net proceeds for working capital and other general corporate purposes.

The following table sets forth a summary of the utilization of the net proceeds from this offering as of June 30, 2022:

Purpose	Percentage to total amount	Net proceeds from the offering $ (million)	Actual use of proceeds up to June 30, 2022 $ (million)	Unutilized amount as of June 30, 2022 $ (million)
fund new business and corporate development and licensing opportunities	30%	245.4	**—**	**245.4**
complete clinical trials and advance new drug candidates	30%	245.4	**45.7**	**199.7**
expand the Company's commercialization efforts	20%	163.6	**63.0**	**100.6**
enhance the Company's global pipeline	15%	122.7	**—**	**122.7**
working capital and other general corporate purposes	5%	40.9	**—**	**40.9**
Total	100%	818.0	**108.7**	**709.3**

The Company plans to gradually utilize the remaining net proceeds in accordance with such intended purpose depending on actual business, which is expect to be fully utilized by the end of 2025.

Use of Net Proceeds from the Global Offering

Dealings in ordinary shares on the Hong Kong Stock Exchange commenced on September 28, 2020. The net proceeds raised from the global offering (the "Global Offering") as described in the prospectus of the Company dated September 17, 2020 (the "Prospectus"), after deduction of the underwriting fees and commissions and other estimated expenses payable by the Company in connection with the Global Offering, were approximately HK$6,636.2 ($850.8 million). As of the date of this announcement, there has been no change in the intended use of net proceeds and the expected timeline as previously disclosed in the section "Use of Proceeds" in the Prospectus. The net proceeds received by the Company from the Global Offering will be used for the following purposes:

- approximately 16.0% will be allocated for ZEJULA to seek indication expansion and hire high-caliber R&D staff dedicated to its development, and to develop and improve the Company's manufacturing facilities to bring ZEJULA to commercialization;

- approximately 6.2% will be used to fund ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications;

- approximately 16.0% will be used for ZEJULA to enhance the Company's commercialization capabilities through increasing its sales and marketing headcounts, among other efforts;

- approximately 8.0% will be used to strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch;

- approximately 11.8% will be used to fund the Company's ongoing and planned clinical trials and preparation for registration filings of other drug candidates in the pipeline, especially late-stage drug candidates;

- approximately 25.0% will be used to explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/ first-in-class assets with clinical validation, synergistic with the Company's current pipeline and aligned to its expertise;

- approximately 7.0% will be used to continue investing in and expanding the Company's internal discovery pipeline and recruit and train talent globally; and

- approximately 10.0% will be used to fund working capital and other general corporate purposes.

The following table sets forth a summary of the utilization of the net proceeds from the Global Offering as of June 30, 2022:

Purpose	**Percentage to total amount**	**Net proceeds from the offering $ (million)**	**Actual use of proceeds up to June 30, 2022 $ (million)**	**Unutilized amount as of June 30, 2022 $ (million)**
for ZEJULA to seek indication expansion and hire high-caliber R&D staff dedicated to its development, and to develop and improve the Company's manufacturing facilities to bring ZEJULA to commercialization	16.0%	136.1	**20.8**	**115.3**
fund ongoing and planned clinical trials and preparation for registration filings of Tumor Treating Fields in multiple solid tumor cancer indications	6.2%	52.7	**14.0**	**38.7**
for ZEJULA to enhance the Company's commercialization capabilities through increasing its sales and marketing headcounts, among other efforts	16.0%	136.1	**64.2**	**71.9**

Purpose	Percentage to total amount	Net proceeds from the offering $ (million)	Actual use of proceeds up to June 30, 2022 $ (million)	Unutilized amount as of June 30, 2022 $ (million)
strengthen commercialization efforts for Tumor Treating Fields through recruiting key talents in relevant indications to drive sales and future potential product launch	8.0%	68.1	**27.1**	**41.0**
fund the Company's ongoing and planned clinical trials and preparation for registration filings of other drug candidates in the pipeline, especially late-stage drug candidates	11.8%	100.4	**100.4**	**—**
explore new global licensing and collaboration opportunities and bring in potentially global best-in-class/ first-in-class assets with clinical validation, synergistic with the Company's current pipeline and aligned to its expertise	25.0%	212.7	**125.3**	**87.4**
continue investing in and expanding the Company's internal discovery pipeline and recruit and train talent globally	7.0%	59.6	**19.8**	**39.8**
fund working capital and other general corporate purposes	10.0%	85.1	**29.0**	**56.1**
Total	100%	850.8	**400.6**	**450.2**

The Company plans to gradually utilize the remaining net proceeds in accordance with such intended purpose depending on actual business, which is expect to be fully utilized by the end of 2025.

Audit Committee Review of Financial Statements

The Audit Committee oversees the accounting and financial reporting processes of the Company and the audits of the Company's financial statements, including but not limited to assisting the Board in its oversight of the integrity of the consolidated financial statements of the Company, the Company's compliance program, and the Company's risk management and internal control over financial reporting. As of the date of this announcement, the Audit Committee currently consists of three members, namely Mr. Scott W. Morrison, Dr. John Diekman, and Mr. Peter Wirth, all of whom are independent directors. Mr. Scott W. Morrison is the chairman of the Audit Committee.

The Audit Committee has reviewed the unaudited consolidated financial statements and interim results of the Company for the six months ended June 30, 2022. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal controls with members of senior management and the external auditor of the Company, KPMG.

Other Board Committees

In addition to the Audit Committee, the Company has a Compensation Committee, a Nominating and Corporate Governance Committee, and a Research and Development Committee.

Important Events after the Reporting Period

No important events affecting the Company have occurred since June 30, 2022 and up to the date of this announcement.

Publication of Interim Results and Interim Report

This interim results announcement is published on the website of the Hong Kong Stock Exchange (www.hkexnews.hk) and the website of the Company (www.zailaboratory.com). The interim report of the Company for the six months ended June 30, 2022 will be published on the aforesaid websites and dispatched to the Company's shareholders in due course.

By order of the Board
Zai Lab Limited
Samantha Du
Director, Chairperson,
and Chief Executive Officer

Hong Kong, August 31, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Samantha Du as a director, and Dr. Kai-Xian Chen, Dr. John Diekman, Ms. Nisa Leung, Mr. William Lis, Mr. Leon O. Moulder, Jr., Mr. Peter Wirth, Mr. Scott W. Morrison, and Richard Gaynor, M.D. as independent directors.

* *For identification only*