

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



SciClone Pharmaceuticals (Holdings) Limited

賽生藥業控股有限公司 *

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6600)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2021

The board of directors (the “**Board**”) of SciClone Pharmaceuticals (Holdings) Limited (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (the “**Group**” or “**we**”) for the year ended December 31, 2021. These results have been audited by the Company’s Auditor in accordance with International Standard on Auditing. In addition, the results have also been reviewed by the Company’s Audit Committee.

HIGHLIGHTS

Financial Highlights

For the year ended December 31, 2021, the Group recorded the following audited results:

- **Revenue** of approximately RMB2,518.5 million was up approximately 31.3% on the prior year, a record growth in the past four years driven by brisk sales of our proprietary product Zadaxin and commercial launch of in-licensed products;
- **Gross profit** grew by approximately 29.7% to approximately RMB1,933.0 million from approximately RMB1,490.5 million for the year ended December 31, 2020;
- **Net profit** was approximately RMB923.4 million, representing an increase of approximately 22.5% over the last year;
- **Basic earnings per share** attributable to owners of the Company were approximately RMB1.42, approximately 2.9% higher than that of the last year;
- **Diluted earnings per share** attributable to owners of the Company were approximately RMB1.33, approximately 1.5% lower than that of the last year;
- The change of basic and diluted earnings per share was not in line with net profit increase, which was primarily due to issuance of new shares when the Company was listed on the Main Board of the Stock Exchange on March 3, 2021;
- The Board recommended a final dividend of HKD0.35 per share for the year ended December 31, 2021.

* For identification purpose only

Business Highlights

On March 3, 2021, the Company was successfully listed on the Main Board of the Stock Exchange, which marked a new beginning of our journey for high-quality development. We, by focusing on innovation, further validated our commercialization capabilities and expedited the product developments to achieve a strong financial performance and nurture the long-term quality growth of our business.

— Star product continued to shine with notable sales growth:

- **Zadaxin:** Zadaxin is our proprietary product and the first branded thymalfasin drug approved in multiple countries including China. Revenue from sales of Zadaxin increased by RMB409.8 million, or 26.1% to RMB1,978.0 million for the year ended December 31, 2021, in spite of the high sales base in the year of 2020 for the prevention and clinical treatment of COVID-19 in China. The continued growth was contributed by the increasing demand from patients and our efforts in expanding Zadaxin's clinical adoptions and upgrading innovative "Go-To-Patient" ("GTP") model:
 - ✓ Results of two Zadaxin studies were published and other clinical studies were progressed as scheduled. Zadaxin was included in five more treatment guidelines and consensuses in 2021;
 - ✓ Explored to integrate internet hospital into GTP model, cooperated with leading DTP pharmacy chains, commercial insurance companies and other innovative service providers, and entered into new retail sales channels to enrich our commercialization capabilities.

— New products enriched our innovative drug portfolio:

- **Zometa:** After completing the transfer of Import Drug License (the "IDL") for Zometa and becoming the Marketing Authorization Holder (the "MAH") of Zometa in China in January 2021, we started converting distributor of all provinces from Novartis to the Company gradually and completed the transfer in the last province in the second half of 2021. Total product revenue of Zometa we generated as registered distributor was RMB169.8 million for the year ended December 31, 2021 while it was RMB4.7 million last year when we were authorized by Novartis as the importer and distributor in certain provinces. Those sales by Novartis we recognized through profit transferred from Novartis in other income.
- **DANYELZA[®] (naxitamab):** Benefited from policy support and local hospitals' cooperation, the Company had the pilot launch of DANYELZA[®] (naxitamab) for the treatment of patients with relapsed/refractory high-risk neuroblastoma in Hainan Bo'ao Lecheng International Medical Tourism Pilot Zone and China (Tianjin) Pilot Free Trade Zone in June and December 2021, respectively. In October 2021, DANYELZA[®] (naxitamab) was included in the list of overseas special drugs of Jing Hui Bao (京惠保), which further improved the accessibility of this innovative drug to patients in China. Except for selling to Hainan and Tianjin, in January 2022, DANYELZA[®] (naxitamab) started to generate revenue from Taiwan based on local special import policy.
- **Oravig:** Oravig, a miconazole buccal tablet (MBT) used to treat oropharyngeal candidiasis (OPC), was officially marketed in China in November 2021. Oravig is the first innovative drug that we completed Phase III trial in China and obtained the approval from the National Medical Products Administration (the "NMPA") for commercialization. Its successful launch manifested our capabilities in product development. As Oravig has more retail and recurring patient needs, it enjoys significant synergy with Zadaxin to utilize our existing retail sales channels through GTP and new retail channels such as Ali Health and JD Health. It is available for purchase in more than 30 cities.

— **Pipeline products accomplished several key development milestones:**

- **RRx-001:** RRx-001 is a potential first-in-class next generation small molecule immunotherapeutic that targets the CD47 to treat various solid tumors. The Phase II clinical trial in the third line and beyond small cell lung cancer (“**SCLC**”) demonstrated favorable efficacy and remarkably benign safety profile. In July 2021, the NMPA approved the investigation new drug (“**IND**”) application of RRx-001 Multi-Regional Clinical Trials (“**MRCT**”) Phase III study in SCLC in China, which we submitted in March 2021. The IND approval kept RRx-001 outpacing other CD47 targeted candidates globally in the field of solid tumor treatment. The Company has been laying the groundwork for coming patient recruitment.
- **DANYELZA[®] (naxitamab):** Within just seven months after U.S. Food and Drug Administration (the “**FDA**”)’s approval, the Company submitted Biologics License Application (“**BLA**”) of DANYELZA[®] (naxitamab) for the treatment of patients with relapsed/refractory high-risk neuroblastoma to the NMPA in China in July 2021. The accelerated timelines of filing BLA in China proved our development capabilities and commitments to bring innovative therapies to fulfill unmet medical needs in China. In September 2021, the BLA was granted priority review. We also submitted BLA in Macau in September 2021.
- **Omburtamab:** In April 2021, our partner Y-mAbs Therapeutics, Inc. submitted its Marketing Authorization Application (“**MAA**”) to the Europe Medicines Agency (the “**EMA**”) for omburtamab, an anti-B7-H3 antibody, for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.
- **Vibativ:** In September 2021, the Company submitted new drug application (“**NDA**”) to the NMPA for Vibativ, a rapidly bactericidal lipoglycopeptide antibiotic, for treating HABP/VABP complicated skin and skin structure infections.

— **New in-licensed product bolstered our differentiated and innovative pipeline:**

- **HSP90-PI3K SMDC:** In September 2021, the Company licensed in a preclinical-stage product portfolio of miniature drug conjugates that consists of a phosphoinositide 3-kinase (“**PI3K**”) inhibitor (undisclosed) payload moiety, a linker and a heat shock protein 90 (“**HSP90**”) binding moiety from Tarveda Therapeutics, Inc. (“**Tarveda**”). This product portfolio demonstrated rapid and sustained tumor accumulation of the conjugate, deep pathway inhibition, and superior efficacy than the PI3K inhibitor on its own according to the preclinical study results. With HSP90-PI3K SMDC and PEN-866, a potential first-in-class HSP90-binding miniature drug conjugate we also licensed from Tarveda in 2020, the Company has built a differentiated and innovative product pipeline in treating solid tumors.

— **Capital market recognized the Company’s investment value and growth prospects:**

- The Company was included as an eligible stock of Shenzhen-Hong Kong Stock Connect in September 2021, which helped further expand our shareholder base and increase the trading liquidity of the shares of the Company.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

		Year ended December 31,	
		2021	2020
	Notes	RMB'000	RMB'000
Revenue	2	2,518,474	1,918,562
Cost of revenue		(585,468)	(428,106)
Gross profit		1,933,006	1,490,456
Sales and marketing expenses		(579,163)	(456,389)
Administrative expenses		(206,457)	(216,220)
Research and development (“R&D”) expenses		(134,389)	(75,420)
Other income		42,833	139,204
Other expenses		(16,842)	(75,173)
Other gains, net		19,118	28,465
Operating profit		1,058,106	834,923
Finance income		7,958	11,478
Finance costs		(40,191)	(29,592)
Finance cost, net		(32,233)	(18,114)
Profit before income tax		1,025,873	816,809
Income tax expense	3	(102,512)	(63,114)
Profit for the year attributable to owners of the Company		923,361	753,695
Other comprehensive income			
<i>Items that will not be reclassified to profit or loss</i>			
Changes in the fair value of equity investments at fair value through other comprehensive income (“FVOCI”)		103,671	153,247
Currency translation differences of the Company		(145,354)	(533,651)
<i>Items that may be subsequently reclassified to profit or loss</i>			
Currency translation differences of the Company’s subsidiaries		110,312	542,819
Total comprehensive income for the year		991,990	916,110
Total comprehensive income attributable to:			
Owners of the Company		991,990	916,110
Earnings per share attributable to owners of the Company (RMB)			
Basic earnings per share	5	1.42	1.38
Diluted earnings per share		1.33	1.35

CONSOLIDATED BALANCE SHEETS

		As at December 31,	
		2021	2020
	Notes	RMB'000	RMB'000
Assets			
Non-current assets			
Right-of-use assets		21,983	8,810
Property, plant and equipment		7,895	5,454
Intangible assets	6	606,095	652,691
Financial assets at fair value through profit or loss (“FVPL”)		91,524	55,936
Financial assets at FVOCI		329,449	232,352
Deferred tax assets		1,520	13,336
Other assets		5,156	5,151
Total non-current assets		1,063,622	973,730
Current assets			
Inventories		174,660	171,585
Trade receivables	7	546,512	324,791
Other current assets		90,212	60,416
Financial assets at FVPL		60,188	70,013
Cash and cash equivalents		2,127,488	1,118,986
Restricted cash		—	163,123
Total current assets		2,999,060	1,908,914
Total assets		4,062,682	2,882,644
Equity and liabilities			
Liabilities			
Non-current liabilities			
Borrowings		762,160	1,171,489
Deferred tax liabilities		14,981	9,258
Lease liabilities		11,175	2,070
Other non-current liabilities		188	194
Total non-current liabilities		788,504	1,183,011

CONSOLIDATED BALANCE SHEETS (continued)

		As at December 31	
		2021	2020
	Notes	RMB'000	RMB'000
Current liabilities			
Trade and other payables	8	537,802	514,098
Lease liabilities		11,391	6,402
Borrowings		382,542	782,988
Current tax liabilities		25,035	84,283
		<u>956,770</u>	<u>1,387,771</u>
Total current liabilities		<u>956,770</u>	<u>1,387,771</u>
Total liabilities		<u>1,745,274</u>	<u>2,570,782</u>
Net assets		<u>2,317,408</u>	<u>311,862</u>
Equity attributable to owners of the Company			
Share capital		232	192
Share premium		1,727,026	—
Other equity		(3)	—
Other reserves		299,759	162,673
Retained earnings		290,394	148,997
		<u>2,317,408</u>	<u>311,862</u>
Total equity		<u>2,317,408</u>	<u>311,862</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. BASIS OF PREPARATION

The consolidated financial statements have been prepared in accordance with all applicable International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board (“IASB”). The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at FVPL or FVOCI which are carried at fair value.

The preparation of financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group’s accounting policies.

Inter-company transactions, balances and unrealized gains/losses on transactions between group companies are eliminated on consolidation.

— *New and amended standards adopted by the Group*

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing 1 January 2021:

Standards	Effective for annual periods beginning on or after
COVID-19-Related Rent Concessions — amendments to IFRS 16	January 1, 2021
Interest Rate Benchmark Reform — Phase 2 — amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16.	January 1, 2021

The amendments listed above did not have any impact on the amounts recognized in prior periods and are not expected to significantly affect the current or future periods.

— *New standards and interpretations not yet adopted*

Standards, amendments and interpretations that have been issued but not yet effective and not been early adopted by the Group are as follows:

Standards	Effective for annual periods beginning on or after
Amendments to IFRS 3, “Reference to the Conceptual Framework”	January 1, 2022
Amendments to IAS 37, “Onerous Contracts — Cost of Fulfilling a Contract”	January 1, 2022
Annual improvements to IFRS standards 2018–2020	January 1, 2022
Amendment to IAS 16, “Property, Plant and Equipment: Proceeds before intended use”	January 1, 2022
IFRS 17, “Insurance Contracts”	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2 — Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 1 — Classification of Liabilities as Current or Non-current	January 1, 2023
Amendments to IAS 8 — Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12 — Deferred Tax related to Assets and Liabilities arising from a Single Transaction Tax ..	January 1, 2023
Amendments to IFRS 10 and IAS 28, “Sale or Contribution of Assets between An Investor and Its Associate or Joint Venture”	To be determined

The directors have performed assessment on the new standards and amendments, and has concluded on a preliminary basis that these new standards and amendments would not have a significant impact on the Group’s consolidated financial statements when they become effective.

2. REVENUE

Year ended December 31,
2021 2020
RMB'000 RMB'000

Recognized at a point in time

— Product sales

2,518,474 1,918,562

3. INCOME TAX EXPENSE

The income tax expense of the Group are analyzed as follows:

Year ended December 31,
2021 2020
RMB'000 RMB'000

Current income tax

84,973 73,432

Deferred income tax

17,539 (10,318)

Income tax expense

102,512 63,114

The income tax provision of the Company's subsidiaries established in China was calculated at tax rate of 25% (year ended 2021: 25%) on the assessable profits for the periods presented, based on the existing legislation, interpretations and practices in respect thereof.

The Company and some of its subsidiaries are incorporated in the Cayman Islands as exempted companies with limited liability under the Companies Act of the Cayman Islands and accordingly, are exempted from Cayman Islands income tax.

Entities incorporated in Hong Kong are subject to a two-tiered profits tax regime, under which the tax rate is 8.25% for assessable profits in the first HKD2 million and 16.5% for any assessable profits in excess.

According to the applicable PRC tax regulations, dividends distributed by a company established in the PRC to a foreign investor with respect to profits derived after January 1, 2008 are generally subject to a 5% or 10% withholding income tax, depending on the country incorporation of the foreign investors. The Group has recognized deferred tax liabilities at 5% withholding tax rate for undistributed profits of its subsidiaries in the PRC in accordance with the double taxation treaty arrangement between the PRC and Hong Kong.

4. DIVIDENDS

Year ended December 31,
2021 2020
RMB'000 RMB'000

Dividends payable at beginning of the year

52,199 —

Declaration of dividends during the year

776,520 2,230,394

Dividends paid during the year

(827,303) (2,173,758)

Exchange differences

(1,416) (4,437)

Dividends payable at end of the year

— 52,199

In February 2021, the Company declared dividends of RMB776,520,000 to then shareholders of the Company. The Company fully paid such dividends on March 2, 2021, the date before its listing on the Main Board of the Stock Exchange.

5. EARNINGS PER SHARE

- (a) Basic earnings per share is calculated by dividing the profit attributable to owners of the Company by the weighted average number of ordinary shares in issue during the respective year.

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Profit for the year attributable to owners of the Company	923,361	753,695
Weighted average number of ordinary shares in issue (thousand shares)	651,801	547,981
	<hr/>	<hr/>
Basic earnings per share (expressed in RMB per share)	1.42	1.38
	<hr/>	<hr/>

- (b) Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assumed conversion of all dilutive potential ordinary shares. For the years ended December 31, 2021 and 2020, diluted earnings per share was calculated by considering the ordinary shares issuable upon the exercise of outstanding share options (using the treasury stock method).

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Profit for the year attributable to owners of the Company	923,361	753,695
Weighted average number of ordinary shares in issue (thousand shares)	651,801	547,981
Diluted impact of share option	43,558	11,432
	<hr/>	<hr/>
Weighted average number of ordinary shares for diluted earnings per share (thousand shares)	695,359	559,413
	<hr/>	<hr/>
Diluted earnings per share	1.33	1.35
	<hr/>	<hr/>

6. INTANGIBLE ASSETS

	License RMB'000	Software RMB'000	Total RMB'000
At January 1, 2020			
Cost	170,381	12,981	183,362
Accumulated amortization	(5,302)	(8,809)	(14,111)
Net book amount	<u>165,079</u>	<u>4,172</u>	<u>169,251</u>
Year ended December 31, 2020			
Opening net book amount	165,079	4,172	169,251
Exchange differences	(40,282)	(81)	(40,363)
Additions	627,363	1,379	628,742
Amortization charge	(83,040)	(2,272)	(85,312)
Impairment losses	(19,627)	—	(19,627)
Closing net book amount	<u>649,493</u>	<u>3,198</u>	<u>652,691</u>
Year ended December 31, 2020			
Cost	753,239	14,360	767,599
Accumulated amortization	(84,171)	(11,162)	(95,333)
Impairment losses	(19,575)	—	(19,575)
Net book amount	<u>649,493</u>	<u>3,198</u>	<u>652,691</u>
At January 1, 2021			
Cost	753,239	14,360	767,599
Accumulated amortization	(84,171)	(11,162)	(95,333)
Impairment losses	(19,575)	—	(19,575)
Net book amount	<u>649,493</u>	<u>3,198</u>	<u>652,691</u>
Year ended December 31, 2021			
Opening net book amount	649,493	3,198	652,691
Exchange differences	(13,891)	(29)	(13,920)
Additions ⁽¹⁾	114,687	3,632	118,319
Impairment losses	(57,104)	—	(57,104)
Amortization charge	(90,884)	(3,007)	(93,891)
Closing net book amount	<u>602,301</u>	<u>3,794</u>	<u>606,095</u>
Year ended December 31, 2021			
Cost	854,569	17,992	872,561
Accumulated amortization	(176,037)	(14,198)	(190,235)
Impairment losses	(76,231)	—	(76,231)
Net book amount	<u>602,301</u>	<u>3,794</u>	<u>606,095</u>

- (1) Addition of intangible assets in the year ended December 31, 2021 was due to the Group's acquisition of the license of HSP90-PI3K SMDC and milestone payments for in-licensed pipeline drugs including DANYELZA[®] (naxitnab) and Oravig.

7. TRADE RECEIVABLES

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
Trade receivables	546,512	324,791
Less: allowance for impairment of trade receivables	—	—
Trade receivables — net	<u>546,512</u>	<u>324,791</u>

(a) Aging analysis of trade receivables based on the invoice date is as follows:

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
Up to 6 months	546,512	307,824
6 to 12 months	—	914
More than one year	—	16,053
	<u>546,512</u>	<u>324,791</u>

The Group's trade receivables are generally collectible within 90 days from the invoice date. No interest is charged on the trade receivables.

(b) Trade receivables were denominated in following currencies:

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
RMB	545,665	323,766
USD	260	422
HKD	587	603
	<u>546,512</u>	<u>324,791</u>

(c) The Group applies the IFRS 9 simplified approach to measuring expected credit losses of trade receivables, which requires expected lifetime losses to be recognized from initial recognition. The expected loss rates are based on the payment profiles of related customers and the corresponding historical credit losses. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

As at December 31, 2021, the expected credit loss was minimal as these receivables had no history of default, most amount of trade receivables were subsequently settled, and there was no unfavorable current condition and forecast future economic condition identified. The Group considered the impact of COVID-19 and incorporated related forward-looking factors to measure expected credit losses as at December 31, 2021 and determined that the expected credit loss remained to be minimal as at December 31, 2021.

8. TRADE AND OTHER PAYABLES

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables (a)	126,920	57,546
Payables for purchase of a license	95,636	163,123
Payables for marketing and promotion expenses	87,948	78,340
Salaries and bonus payable	92,878	81,214
Payables for testing and clinical trial fees for R&D	48,369	15,871
Payables for professional service fee	29,706	15,216
Payables for listing expenses	—	26,790
Dividends payable	—	52,199
Others	56,345	23,799
	<u>537,802</u>	<u>514,098</u>

(a) Aging analysis of the trade payables based on invoice date at the respective balances sheet dates are as follows:

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Less than 1 year	<u>126,920</u>	<u>57,546</u>

FINANCIAL HIGHLIGHTS

The Covid-19 pandemic has imposed a profound impact on the world in every aspect and accelerated many of the trends, such as innovation in drug development, digitalization, and healthcare consumerization. Our rapid adaption to these swift changes positioned us well for continuous growth in 2021 and beyond. We achieved fast development of potential first-in-class drug candidates, incorporated internet hospital and new retail channels to our innovative GTP model, and integrated robust value added services to enhance patient experience.

Our revenue of RMB2,518.5 million for the year ended December 31, 2021 was up by 31.3% on the prior year, a record growth in the past four years driven by brisk sales of our proprietary product Zadaxin and commercial launch of in-licensed products. Our gross profit grew to RMB1,933.0 million for the year ended December 31, 2021 from RMB1,490.5 million for the last year, representing a year-on-year increase of 29.7%. Our profit for the year attributable to owners of the Company was RMB923.4 million for the year of 2021, as compared with RMB753.7 million for the last year.

These strong results demonstrated that our strategy is driving the standards of excellence in our business performance that have always characterized our products and services.

BUSINESS REVIEW

We are a biopharmaceutical company with an integrated platform for product development and commercialization. We strategically focus on some of the largest and fast-growing therapeutic areas with significant unmet medical needs in China, primarily including oncology and severe infection.

Leveraging our integrated platform, we have established a balanced product portfolio focusing on high potential therapeutic areas, led by marketed products with strong cash generation ability through effective lifecycle management and novel GTP model, and supported by an innovative pipeline with first-in-class/best-in-class potential to drive sustainable long-term growth.

Our Marketed Products

For the year ended December 31, 2021, our marketed products comprised of (i) our proprietary product, Zadaxin; (ii) our in-licensed products; and (iii) promotion products on behalf of our business partners in China.

- ***Sales of our proprietary product, Zadaxin:***

We developed Zadaxin in the early 1990s and obtained the approval for its sales in the China market in 1996. As the first branded thymalfasin drug in China, Zadaxin possesses the advantage of its strong brand recognition and product loyalty from the doctors and target patients, the majority of whom are self-paying or covered by private medical insurance. For the year ended December 31, 2021, we generated our revenue primarily through the sales to our exclusive importer and distributor in China. With our effective lifecycle management and development of innovative GTP model, sales of Zadaxin continued to achieve strong growth for the year ended December 31, 2021, increasing by 26.1% to RMB1,978.0 million, despite the high base of Zadaxin sales for prevention and clinical treatment of COVID-19 in China for the year ended December 31, 2020.

1) *Lifecycle management:*

Zadaxin's sustainable growth is driven by our ongoing clinical studies and academic promotions to expand its clinical adoptions.

We have been sponsoring investigators to conduct randomized controlled trials (“**RCT**”) and real-world studies (“**RWS**”) to discover Zadaxin's potential clinical adoptions in oncology, severe infection, vaccine and other therapeutic areas. Major results for 2021 are as follows:

- ✓ A retrospective study in 5,746 patients published in 2021 Issue 22 of Chinese Medical Journal proved thymosin $\alpha 1$ (Ta1) therapy significantly improved the 5-year disease-free survival (“**DFS**”) and overall survival (“**OS**”) rate in patients with non-small cell lung cancer (“**NSCLC**”) after R0 resection;
- ✓ A propensity score matching analysis of 468 patients published in Medicine (Baltimore) in May 2021 demonstrated Ta1 therapy improved postoperative survival after curative resection for solitary hepatitis B virus-related hepatocellular carcinoma;
- ✓ Preliminary analyses of RCT for sepsis in 1,106 patients and RCT for pancreatitis in 504 patients have been completed and are in preparation for publication;
- ✓ Completed 60% patient enrolment of RCT of Ta1 combined with PD-1 antibody and apatinib in advanced gastric cancer;
- ✓ Initiated the clinical study on COVID-19 inactivated vaccine combined with Zadaxin and completed 100% patient enrolment.

As of the date of this announcement, we have more than 10 on-going clinical studies in China and overseas (U.S. and Italy). Based on our efforts in life cycle management of Zadaxin, in addition to official indications (for treatment of chronic hepatitis B and vaccine enhancement in patients with impaired immunity), thymosin $\alpha 1$ has been included in treatment guidelines and consensuses issued by several professional associations including the Chinese Medical Association, the Chinese Society of Clinical Oncology, Chinese Medical Doctor Association and China Anti-Cancer Association, such as for the treatments of:

- ✓ sepsis (2014 and 2020);
- ✓ pancreatic cancer (2019 and 2021*);
- ✓ liver cancer (2017, 2018, 2019 and 2020);
- ✓ COVID-19 (2020);
- ✓ HCC recurrence after hepatectomy (2021*);
- ✓ lymph cancer (2017, 2019 and 2021);
- ✓ TACE (2018 and 2021);
- ✓ CRF (2021);
- ✓ end-stage liver disease complicated with infections (2018 and 2022*);
- ✓ gastric cancer (2022) and others.

* Year of publication

2) *GTP model:*

Our innovative GTP model has contributed significantly to the sales growth of our products through retail channels. It has enhanced accessibility of our products to patients and maximum coverage of patients. With GTP model, patients can upload prescriptions to the e-platform and drugs will be delivered to them directly. GTP is also a platform for the Company to provide value added services to patients such as comprehensive academic and patient education. At 2021 year end, GTP model had more than 131,000 registered patients, more than 81,000 registered doctors and approximately 1,000 DTP pharmacies.

We continued to upgrade our GTP model for the sales of Zadaxin and other products in 2021:

- ✓ Explored to integrate internet hospital into GTP model and launched pilot internet hospital project in Guangdong. We also set up an internet hospital joint venture to further digitalize our business;
- ✓ Strengthened comprehensive cooperation with leading DTP chains in China (Link Pharmacies, Gaoji Health, Medbanks, Yuanxin, Sinopharm Care Plus and “Yiyao” (drug benefiting) Ecosystem of SPH Cloud Health) to expand the coverage of DTP pharmacies;
- ✓ Cooperated with more commercial insurance providers such as LinkDoc and Zhong An Insurance. We also deepened our cooperation with Medi Trust through our strategic relationship with Shanghai Pharma;
- ✓ Started strategic cooperation with Shanghai SF Pharmaceuticals Supply Chain Holdings Co., Ltd., and LinkDoc Technology to build up a more efficient supply chain and better patient service that combines innovative payment solutions with digital service;
- ✓ Entered into the new retail sales channels such as Ali Health and JD Health.

For the year ended December 31, 2021, sales through GTP model contributed to more than 62% of total sales volume of Zadaxin as compared with approximately 53% for the last year. In the last quarter of 2021, the sales volume contribution from GTP was approximately 70%.

• *Sales of our in-licensed products:*

- **Zometa:** Zometa is our marketed in-licensed product indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, and hypercalcemia of malignancy. After completing the transfer of IDL for Zometa and becoming the MAH of Zometa in China in January 2021, we started converting distributor of all provinces from Novartis to the Company gradually and completed the transfer in the last province in the second half of 2021.

The Company has well implemented the academic promotion plan for Zometa in 2021. Based on the clinical studies of Zometa, Zoledronic Acid (the compound of Zometa) was recommended in Guidelines and Standards for Breast Cancer Diagnosis and Treatment (《中國抗癌協會乳腺癌診治指南與規範》2021) and by Chinese Anti-Cancer Association and Chinese Expert Consensus on Bone Health Management in Patients with Early Breast Cancer (《早期乳腺癌患者骨健康管理中國專家共識》2022) for its anti-tumor effect. In June 2021, Zoledronic Acid was also recommended in Expert Consensus on Safety Management of Bone Modifying Drugs (《骨改良藥物安全性管理專家共識》). The inclusion in treatment guidelines and consensus will further increase the demand of Zometa.

In addition to promotion for hospital usage, we also initiated a project of Outpatient Injection Centers Alliance since Q1 2021 to enhance patient access of Zometa outside hospitals and provide value-added services to patients.

Total product revenue of Zometa we generated as registered distributor was RMB169.8 million for the year ended December 31, 2021 while it was RMB4.7 million last year when we were authorized by Novartis as the importer and distributor in certain provinces. Those sales by Novartis we recognized through profit transferred from Novartis in other income.

- **DANYELZA[®] (naxitamab):** In December 2020, we in-licensed DANYELZA[®] (naxitamab) from Y-mAbs Therapeutics, Inc. (“Y-mAbs”). It is used for the treatment of patients (one year of age and older, and adults) with relapsed/refractory high-risk neuroblastoma. Naxitamab was granted priority review, breakthrough therapy designation, and orphan drug designation. It received accelerated approval in the U.S. from the FDA in November 2020.

In order to accelerate provision of this innovative therapy to pediatric patients in China prior to the BLA approval by the NMPA, the Company had pilot launch of DANYELZA[®] (naxitamab) in Hainan Bo’Ao Lecheng International Medical Tourism Pilot Zone and China (Tianjin) Pilot Free Trade Zone in June and December 2021, respectively.

In October 2021, DANYELZA[®] (naxitamab) was included in the list of overseas special drugs of Jing Hui Bao (京惠保), a supplement coverage to basic medical insurance for serious diseases in Beijing, which further improved the accessibility of this innovative drug to patients in China.

Except for selling to Hainan and Tianjin, in January 2022, DANYELZA[®] (naxitamab) started to generate revenue from Taiwan based on local special import policy.

- **Oravig:** Oravig is our marketed in-licensed product indicated for the treatment of patients with oropharyngeal candidiasis. It utilizes patented buccal tablet technology enabling once-daily dosing to provide patients with a convenient treatment option. Oravig is the first innovative drug that we completed Phase III trial in China and obtained the approval from the NMPA in January 2021 for commercialization. Its successful launch in November 2021 manifested our capabilities in product development. As Oravig has more retail and recurring patient needs, it enjoys significant synergy with Zadaxin to utilize our existing retail sales channels through GTP and new retail channels such as Ali Health and JD Health. It is available for purchase in more than 30 cities.
- **Angiomax:** Angiomax is our in-licensed product indicated for use as anticoagulant in patients undergoing percutaneous coronary intervention, including patients with heparin induced thrombocytopenia and thrombosis syndrome. We entered into an agreement with Huizheng (Shanghai) Pharmaceuticals Technology Co., Ltd. (“**Huizheng**”) on August 31, 2020, under which we engaged Huizheng for the promotion and distribution of Angiomax in Mainland China. Angiomax was commercially launched in Q2 2021.
- ***Sales of promotion products on behalf of our business partners***

During 2021, we continued to sell promotion products for our partner pharmaceutical companies, such as Pfizer and Baxter, as a promotor and distributor for such business partners. Revenue from sales of promotion products for business partners increased by RMB20.9 million, or 6.2% from RMB336.3 million for the last year to RMB357.2 million in 2021.

Subsequent to the year end, we have successfully renewed the Five-Year Cooperation Agreement with Baxter and both parties agreed to strengthen the mutual support in the development of pipeline products in the field of oncology and innovative business models.

Our Product Development

In recent years, we started the development of a number of pipeline drug candidates through in-licensing model. We acquire licenses and get involved in the product development process from various stages, ranging from pre-clinical for some of our early-stage pipeline products, to pivotal clinical trials for some of our late-stage pipeline products.

Our efforts in product development have yielded a pipeline of potential drug candidates in different stages of development spanning our key therapeutic areas and also high-value/high-growth sectors: oncology and severe infection. As of December 31, 2021, we have built a portfolio of 8 pipeline drug candidates, 4 of which are in phase III or later stages overseas with a fast-to-market strategy in China, and 4 are in earlier stages of preclinical to phase II clinical trials overseas or in China.

The following table summarizes the mechanism of action, indication(s)/clinical adoptions, and development status of our pipeline assets as of the date of this announcement.

Product Name	Mechanism of Action	Indication(s)/ Clinical Adoptions	Partner	Partner's Overseas Status	China Status
Late stage:					
Vibativ	Dual antibacterial activity on cell wall and cell membrane	HABP/VABP complicated skin and skin structure infections	Cumberland Pharmaceuticals (U.S.)	Marketed	Obtained clinical trial waiver and submitted NDA in September 2021
DANYELZA® (naxitamab)	Targeting GD2	High risk neuroblastoma	Y-mAbs Therapeutics, Inc. (U.S.)	Obtained BLA from FDA in November 2020	Held pilot launch in Bo'Ao and Tianjin; Submitted BLA to the NMPA in July 2021 and submitted BLA in Macau in September 2021
		Relapsed second-line osteosarcoma		US Phase II trial on-going	—
Omburtamab	Targeting B7-H3 — expressing cells	CNS/leptomeningeal metastasis from neuroblastoma	Y-mAbs Therapeutics, Inc. (U.S.)	Submitted MAA to EMA in April 2021	—
RRx-001	Myc inhibitor and antagonist of CD47-SIRPα pathway	Small cell lung cancer	EpicientRx, Inc. (U.S.)	US Phase III trial on-going	Obtained IND approval for Phase III study of 3rd line and beyond SCLC from the NMPA in July 2021
		Colorectal cancer		US Phase II trial (+irinotecan) completed	—
Early stage:					
PEN-866	Mini-conjugate of HSP90-SN38	Solid tumors	Tarveda Therapeutics (U.S.)	US Phase II basket trial on-going	IND filing in preparation
HSP90-PI3K SMDC	Mini-conjugate of HSP90-PI3K	Solid tumors		Pre-clinical	Joint efforts in lead conjugate optimization
PT-112	Platinum-containing compounds	Late stage prostate cancer	Phosplatin Therapeutics (U.S.)	US Phase II trial on-going	Completed Phase I and initiated Phase II trial
		Cholangiocarcinoma		US Phase I trial (+gemcitabine) completed	
ABTL-0812	Akt/mTOR inhibitor	Endometrial/lung/pancreatic cancer	Ability Pharma (Spain)	EU Phase II trial on-going	Obtained IND

- **Key pipeline milestones:**

- ✓ **Vibativ:** Vibativ is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby Vibativ both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. It is approved in the United States and Canada for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *S. aureus*.

Milestones in 2021

In September 2021, the Company submitted NDA to the NMPA for Vibativ for treating HABP/VABP complicated skin and skin structure infections.

- ✓ **DANYELZA[®] (naxitamab):** DANYELZA[®] (naxitamab) is the first humanized, monoclonal antibody targeting GD2, a tumor antigen on the cell surface of neuroblastoma. In addition to demonstrated clinical benefits, DANYELZA[®] (naxitamab) has the advantages of convenient administration and high patient compliance. It has short infusion time (30–60 minutes), which makes it possible to be administered in outpatient setting. There is no requirement of pre-treatment with autologous stem cell transplant or combination with IL-2 (Interleukin-2) therapy when patients receive DANYELZA[®] (naxitamab).

Except for the treatment of patients (one year of age and older, and adults) with relapsed/refractory high-risk neuroblastoma, Y-mAbs is expanding naxitamab's indications such as relapsed second-line osteosarcoma (Phase II trial ongoing).

Milestones in 2021

In July 2021, the Company submitted BLA of DANYELZA[®] (naxitamab) to the NMPA in China, within just seven months after the FDA's approval. The NMPA granted this BLA priority review in September 2021. BLA is subject to the NMPA's approval. In September 2021, we also submitted BLA of DANYELZA[®] (naxitamab) in Macau.

Milestones expected in 2022

We aim to submit BLA of DANYELZA[®] (naxitamab) in Hong Kong in the first half of 2022.

The Company plans to submit IND application in China of DANYELZA[®] (naxitamab) and granulocyte-macrophage colony stimulating factor (“**GM-CSF**”) in combination with irinotecan and temozolomide in patients with high-risk neuroblastoma with primary refractory disease or in first relapse (“**STUDY 203**”). STUDY 203 is an international single-arm, multi-centre, Phase II clinical trial.

- ✓ **Omburtamab:** Omburtamab is another pipeline drug candidate we in-licensed from Y-mAbs in December 2020, which is used to treat CNS/leptomeningeal metastasis from neuroblastoma. Other therapeutic areas under clinical trials by Y-mAbs include diffuse intrinsic pontine glioma (Phase I trial ongoing) and desmoplastic small round cell tumor (Phase II trial ongoing).

Omburtamab targets B7-H3-expressing cells in human solid tumors, including embryonal tumors, carcinomas, sarcomas, and brain tumors, and binds to an FG loop dependent conformation on the B7-H3 molecule, a domain critical for its biologic function. Omburtamab may potentially become the first targeted therapy for pediatric patients with central nervous system (CNS)/leptomeningeal metastasis from neuroblastoma.

Milestones in 2021

In April 2021, our partner Y-mAbs submitted its MAA to the EMA in Europe for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.

Milestones expected in 2022

Y-mAbs completed Pre-BLA meeting with the FDA in February 2022 which provided a clear regulatory path forward for the FDA approval of omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. Y-mAbs aims to resubmit omburtamab BLA by the end of the first quarter 2022 and apply for full approval.

- ✓ **RRx-001:** In June 2020, we in-licensed from EpicentRx, Inc. (“**EpicentRx**”). RRx-001, which was initially identified and sourced from the aerospace industry and has been developed by EpicentRx as a novel first-in-class therapy. RRx-001 is a well-tolerated next generation small molecule immunotherapeutic treating solid tumors. It has the potential to convert platinum- resistant tumors into platinum sensitive tumors and may have wide clinical adoptions as monotherapy or in combination with chemotherapy, immunotherapy, radiation and targeted agents.

Milestones in 2021

In March 2021, the Company submitted IND application of RRx-001 MRCT Phase III study in the 3rd line and beyond SCLC in China to the NMPA. In July 2021, the Company has obtained the IND approval from the NMPA. The Company has been laying the groundwork for coming patient recruitment.

In November 2021, RRx-001 was selected as one of the “Top 10 Innovative Anti-Cancer Drugs with Excellent Potential of the Year 2021” initiated and hosted by 21 New Health Research Institute of 21st Century Business Herald in China.

Milestones expected in 2022

We expect the first patient enrolment in China for this MRCT in the second quarter of 2022. As of the date of this announcement, RRx-001 is globally the only small molecule drug in CD47 signaling pathways, and the only CD47 targeted drug that has entered phase III clinical trials in the field of solid tumor treatment worldwide.

- ✓ **PEN-866:** In March 2020, we in-licensed PEN-866, a potential first-in-class HSP90-binding miniature drug conjugate, from Tarveda. PEN-866 has a differentiated design which is not to inhibit the activity of HSP90 but alternatively bind to the activated form of HSP90 in solid tumors as a SMDC and is linked to the topoisomerase 1 inhibitor (SN-38), a potent anti-cancer payload. Phase I clinical data demonstrated favorable efficacy and safety profile with broad application potential. As of the date of this announcement, there had been no approved SMDCs or relevant ongoing clinical trials in China. There are two SMDC candidates currently undergoing clinical trial worldwide: both are from Tarveda and one of them is PEN-866.

Milestone in 2021

We had in-depth exchange of PEN-866 Phase II clinical data with Tarveda and was in preparation of IND filing in China to conduct China Phase I/II study in lung cancer.

Milestone expected in 2022

The Company plans to submit IND application of PEN-866 phase I/II study in patients with advanced lung cancer to the NMPA in the first half of 2022.

- ✓ **HSP90-PI3K SMDC:** In September 2021, the Company licensed in a preclinical-stage product portfolio of miniature drug conjugates that consists of a PI3K inhibitor (undisclosed) payload moiety, a linker and a HSP90 binding moiety from Tarveda. This product portfolio demonstrated rapid and sustained tumor accumulation of the conjugate, deep pathway inhibition, and superior efficacy than the PI3K inhibitor on its own according to the preclinical study results. With HSP90-PI3K SMDC and PEN-866, the Company has built a differentiated and innovative product pipeline in treating solid tumors.

The Company cannot guarantee that it will be able to develop, or ultimately market, any of the products in its pipeline successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

- ***Establishment of strategic cooperation with research organizations***

Except for the close collaborations with our partners, we also established cooperation with external research organizations to enhance our research and development capabilities.

- ✓ In December 2021, we entered into a strategic partnership with Hangzhou Tigermed Consulting Co., Ltd. (stock code: 300347.SZ/3347.HK). The two parties will work closely to carry out a full range of in-depth cooperation in the field of clinical research and development of innovative drugs;
- ✓ Subsequent to the year-end, we finalized the cooperation with China Pharmaceutical University to set up a joint laboratory, which will be a long-term platform for research and development and talent training for both parties.

- ***Expansion of product development teams:***

While developing with external parties, we also continued to expand our own product development team. Our product development process is carried out through the joint efforts of the Business Development, Research & Development, and Regulatory Affair teams. The teams actively seek to develop and commercialize products focusing on targeted therapies, immunotherapy and enhanced chemotherapy options with first/best-in-class potential.

As of December 31, 2021, our product development teams grew to approximately 100 people (As of December 31, 2020: 80).

Sales, Marketing and Distribution

As of December 31, 2021, our sales and marketing team comprised approximately 720 employees systematically deployed to cover approximately more than 4,000 class III and class II hospitals in China and to capture the latest market dynamics, including approximately 480 employees assigned to the immunology business unit, approximately 200 employees in the oncology business unit and approximately 40 employees responsible for market access and commercial operations. Our sales and marketing team engages in offline and online marketing and promotional activities to generate market demand and build brand recognition for our proprietary, in-licensed (except for Angiomax), and promotion products.

We sell our proprietary, in-licensed, and promotion products through distributors to hospitals and pharmacies in China. Specifically, for our proprietary product, Zadaxin, we recognize revenue through sales to our exclusive importer and distributor in China. In compliance with the “two-invoice system”, after our sales of Zadaxin to the exclusive importer, it clears the products through customs of China as an imported drug and distributes further to hospitals and pharmacies. In November 2021, the Company entered into an import and distribution agreement to engage Shanghai Pharmaceutical Lin-gang Special Area Co., Ltd. (“**Shanghai Pharma Lin-Gang**”), one of our non-substantial shareholders, as our exclusive importer and distributor of Zadaxin in China. Shanghai Pharma Lin-Gang is a wholly-owned subsidiary of Shanghai Pharmaceuticals Holding Co., Ltd., a large pharmaceutical industry group listed on the Shanghai Stock Exchange (stock code: 601607) and Hong Kong Stock Exchange (stock code: 2607) and the largest service provider of imported drugs, vaccines and medical devices in China. For Zadaxin’s overseas sales, such as in South Korea, Thailand, Argentina, Italy and Cambodia, we primarily rely on overseas partners to handle marketing, promotion, sales and distribution.

As for our marketed in-licensed products and 6 promotion products, we import and distribute them through our wholly-owned subsidiary SciClone Pharmaceuticals (Jiangsu) Co., Ltd. (“**SciClone Jiangsu**”). We recognize revenue of the sales of in-licensed products and promotion products to our distributors through the distribution network we manage. As for Angiomax, we recognize revenue of its sales to Huizheng.

Production, Quality Control and Supply Chain

We manufacture our proprietary product, Zadaxin, and our in-licensed product, Angiomax, through Patheon Italia, an industry-leading and highly reputable CMO. We outsourced the production of in-licensed products to our partners, including Novartis for Zometa, Vectan Pharm for Oravig and Y-mAbs for DANYELZA[®] (naxitamab) under the Supply Agreement with them. Our production quality management standards remain complied with GMP in various markets where we have operations.

In 2021, despite the pandemic pressure on international supply chain, we managed well with our overseas CMO, partners and logistics companies to make sure stable and healthy supply for demands in China and other countries.

Impacts of Significant Policies with Respect to Pharmaceutical Industry

During 2021 and as of the date of this announcement, a number of reform policies were issued in China pharmaceutical industry, and the volume-based procurement (“**VBP**”) remained the most influential one for the operation of pharmaceutical companies.

✓ *Zadaxin:*

Thymalfasin was listed in the catalog for the fifth batch of VBP in April 2021. In June 2021, we participated in the fifth batch of VBP for thymalfasin with Zadaxin but Zadaxin did not win the bid. The bid was won by four generic thymalfasin drugs, produced by ShuangCheng Pharmaceuticals, Yangtze River Pharmaceuticals, Sinopep Allsino Biopharmaceutical Co., and Hanyu Pharmaceuticals, respectively. As a result, such four bid-winning generic thymalfasin will be procured by public hospitals and other public medical institutions with priority, enabling them to increase their market share. However, Zadaxin can still be prescribed by doctors at public hospitals and other public medical institutions for patients in compliance with relevant prescription regulations, or be purchased at pharmacies.

Zadaxin is the first branded thymalfasin drug approved in China in 1996. With the first mover advantage and proven efficacy, Zadaxin has been able to maintain strong brand recognition and product loyalty from the doctors and target patients, especially for its potential benefits in treating SARS and COVID-19. Most of the patients are self-paying or covered by private medical insurance. We expect Zadaxin continues to enjoy its competitive edge as we continue to diversify our sales through retail pharmacies, expand Zadaxin’s clinical adoptions through life cycle management, and collaborate with commercial insurance companies and other innovative payment solutions providers to increase Zadaxin’s insurance coverage.

Based on the actual sales in the second half of 2021 and subsequent to the 2021 year-end, we believe that our overall business, results of operations and financial conditions was not and will not be materially affected by the exclusion of Zadaxin from the VBP.

✓ *Zometa:*

On January 21, 2022, National Joint Procurement Office (the “**NJPO**”) released drug list for the seventh batch of VBP. Zoledronic Acid injection, the compound for our product Zometa, was on the list. We believe that our overall business, results of operations and financial conditions will not be materially affected by the seventh batch of VBP:

- 1) Currently Zometa’s market share is not high in China’s bone metastasis market. If Zometa is successfully included in VBP, its sales volume will increase significantly, which will drive further growth of Zometa. If Zometa loses the bid, Zometa can still be prescribed by doctors at public hospitals and other public medical institutions for patients in compliance with relevant prescription regulations and we consider the room is sufficient for Zometa to continue to grow;
- 2) Regardless whether Zometa is included in VBP, we have identified new areas of development for Zometa such as bone health management in patients with early breast cancer, which is supported by clinical studies of Zometa and paid by patients’ own pockets or covered by private medical insurance;
- 3) We have been developing our project of Outpatient Injection Centers Alliance since Q1 2021 to enhance patient access of Zometa outside hospitals and provide value-added services to patients.

We will formulate our optimal strategy and choose to participate or not to participate in the VBP bidding depending on our balancing of various factors including the price level, sales volume and market shares.

OUTLOOK

China has been rebalancing its economy towards services, innovation and consumption driven growth while addressing inequity and supporting industries such as healthcare, technology and e-commerce. Looking out to 2022, we will continue to align our development strategy with the government's aims of building a more innovative and productive economy and healthcare industry.

Top priorities in 2022:

- Strengthen marketed product portfolio:
 - 1) Implement Internet Hospital Model to further address patient access of Zadaxin and other products, with multiple service providers for broad coverage;
 - 2) Drive clinical evidence analysis and publication on Zadaxin in severe infection;
 - 3) Continue to invest in outpatient injection centers and private hospitals to promote Zometa;
 - 4) Renew partnership with Pfizer;
- Accelerate product pipeline:
 - 1) Obtain BLA approval of DANYELZA[®] (naxitamab) and continue driving patient adoption in multiple pilot zones before commercial launch;
 - 2) Initiate Phase III study of RRx-001 and Phase I/II study of PEN-866;
 - 3) License-in assets in oncology and severe infection to fulfill unmet medical needs in China;
- Enhance product development capabilities:
 - 1) Establish the Scientific Advisory Board to support proactive screening system for new assets;
 - 2) Scale up in-house research and clinical development capability through multiple global studies;
- Look for merger and acquisition opportunities:
 - 1) Develop a merger and acquisition strategy that supports the Company's goal of becoming a leading specialty pharma in oncology and severe infections;
 - 2) Actively search for potential acquisition targets;
- Integrate talent strategy:
 - 1) Update SciClone Talent Portrait as guidance for talent recruitment and development.

MANAGEMENT DISCUSSION AND ANALYSIS

	Year ended December 31,			
	2021		2020	
	<i>RMB million</i>	<i>%</i>	<i>RMB million</i>	<i>%</i>
Revenue	2,518.5	100.0	1,918.6	100.0
Cost of revenue	(585.5)	(23.2)	(428.1)	(22.3)
Gross profit	1,933.0	76.8	1,490.5	77.7
Selling and marketing expenses	(579.2)	(23.0)	(456.4)	(23.8)
Administrative expenses	(206.4)	(8.2)	(216.2)	(11.3)
R&D expenses	(134.4)	(5.3)	(75.4)	(3.9)
Other income	42.8	1.7	139.2	7.3
Other expenses	(16.8)	(0.7)	(75.2)	(3.9)
Other gains, net	19.1	0.8	28.5	1.5
Operating profit	1,058.1	42.0	834.9	43.5
Finance income	8.0	0.3	11.5	0.6
Finance costs	(40.2)	(1.6)	(29.6)	(1.5)
Finance costs, net	(32.3)	(1.3)	(18.1)	(0.9)
Profit before income tax	1,025.9	40.7	816.8	42.6
Income tax expenses	(102.5)	(4.0)	(63.1)	(3.3)
Profit for the year attributable to the owner of the Company	923.4	36.7	753.7	39.3

Revenue

	Year ended December 31,			
	2021		2020	
	<i>RMB million</i>	<i>%</i>	<i>RMB million</i>	<i>%</i>
Proprietary product	1,978.0	78.5	1,568.2	81.7
Promotion products for business partners	357.2	14.2	336.3	17.5
In-licensed product	183.3	7.3	5.9	0.4
DC Bead	—	—	8.1	0.4
Total	<u>2,518.5</u>	<u>100.0</u>	<u>1,918.6</u>	<u>100.0</u>

For the year ended December 31, 2021, revenue was approximately RMB2,518.5 million, representing an increase of approximately 31.3% over the last year, a record growth in the past four years driven by brisk sales of our proprietary product Zadaxin and commercial launch of in-licensed products.

Proprietary product

Zadaxin is our proprietary product. The expansion of clinical adoptions through life cycle management, the increased recognition of clinical benefits from physicians and patients especially after COVID-19 pandemic, and the trend of online healthcare service through GTP model, fueled the sustainable growth of Zadaxin.

Revenue from sales of Zadaxin increased by RMB409.8 million, or 26.1% from RMB1,568.2 million for the last year to RMB1,978.0 million in 2021, despite the high base of Zadaxin sales for the prevention and clinical treatment of COVID-19 in China for the year ended December 31, 2020.

In-licensed product

Zometa is our in-licensed product from Novartis. As authorized by Novartis, we began distributing Zometa as the importer and distributor in certain provinces in China since December 2020 and thereby started recording as part of revenue from our sales of Zometa. After completion of IDL transfer in January 2021, we became MAH of Zometa. We generated product revenue of RMB169.8 million for the year ended December 31, 2021. Zometa was partially sold through the distribution network of Novartis before the completion of the conversion of distributor from Novartis to SciClone Jiangsu in the second half of 2021. Therefore we recognized those sales by Novartis through profit transferred from Novartis in other income.

Promotion products for business partners

Our promotion products for business partners include Farlutal, Methotrexate, and Estracyt, which we promote and sell for Pfizer, and Holoxan, Mesna and Endoxan, which we promote and sell for Baxter. Revenue from sales of promotion products for business partners increased by RMB20.9 million, or 6.2% from RMB336.3 million for the last year to RMB357.2 million in 2021.

The increase reflected our efforts in sales and marketing activities to enhance brand recognition of our promotion products. In 2021, the number of hospital visits and operations by patients recovered from COVID-19 pandemic as many hospitals in China allocated significant resources to contain COVID-19 and patients suffering from other diseases generally avoid going to hospital to prevent being infected in 2020.

Cost of revenue

Our cost of revenue increased by 36.8% to RMB585.5 million in 2021 from RMB428.1 million for the last year. Among the increase of cost of revenue, the rise of product costs and freight costs generally followed the growth of sales of Zadaxin, Zometa and promotion products. The surge of amortization of intangible assets was resulted from Zometa's IDL transfer in January 2021. We started to recognize Zometa's partial amortization of intangible assets in the cost of revenue corresponding to our product revenue of Zometa in 2021, while we recorded the full amortization of RMB35.2 million in other expenses in 2020.

The following table sets forth our cost of revenue by amount, as a percentage of total cost of revenue and as a percentage of total revenues for the years indicated:

	Year ended December 31,					
	2021			2020		
	<i>RMB million</i>	<i>%</i>	<i>% of Revenue</i>	<i>RMB million</i>	<i>%</i>	<i>% of Revenue</i>
Product costs	416.6	71.2	16.5	364.5	85.1	19.0
Amortization of intangible assets	74.0	12.6	2.9	7.8	1.8	0.4
Freight costs	37.8	6.5	1.5	34.5	8.1	1.8
Warehouse costs	17.9	3.1	0.7	14.8	3.5	0.8
Others	39.2	6.6	1.6	2.4	1.5	0.3
Total	<u>585.5</u>	<u>100.0</u>	<u>23.2</u>	<u>428.1</u>	<u>100.0</u>	<u>22.3</u>

Our gross profit increased by RMB442.5 million, or 29.7%, to RMB1,933.0 million in 2021 from RMB1,490.5 million for the last year, and our gross margin decreased by 0.9 ppt to 76.8% in 2021 from 77.7% for the last year, primarily resulted from a change of our product mix. In 2021 we generated top-line revenue from Zometa, while Zometa had lower gross margin compared with Zadaxin as it incurred amortization cost of intangible assets.

Selling and Marketing Expenses

Our selling and marketing expenses increased by 26.9% to RMB579.2 million for the year ended December 31, 2021 from RMB456.4 million for the last year, which was mainly due to: 1) the low base in 2020 when market development and business promotion activities were interrupted by the outbreak of COVID-19; 2) rise of employee benefits along with the expansion of our sales and marketing team. Promotion related expenses and employee benefits increased by RMB41.8 million and RMB63.0 million respectively.

General and Administrative Expenses

Our general and administrative expenses decreased by 4.5% to RMB206.4 million for the year ended December 31, 2021 from RMB216.2 million for the last year, which was primarily attributable to the decline of listing expenses as the Company was listed on March 3, 2021.

Research and Development Expenses

Our research and development expenses increased by 78.2% to RMB134.4 million for the year ended December 31, 2021 from RMB75.4 million for the last year.

During the year of 2021, testing and clinical trial expenses increased by RMB44.1 million or 154.6%, as expenses of several key research and development projects such as RRx-001, DANYELZA®(naxitamab) and Zadaxin grew compared with the prior year, resulted from the progressing of research and registration. In addition, with expansion of research and development team, employee benefit increased by RMB10.8 million or 30.1%.

Other Income and Other Expenses

Our other income decreased to RMB42.8 million for the year ended December 31, 2021 from RMB139.2 million for the last year, primarily because: i) there was decrease in licensing income of Zometa product resulting from our licensing arrangement with Novartis. After the completion of the conversion of distributor from Novartis to SciClone Jiangsu in the second half of 2021, we recognized all sales of Zometa in the product revenue; ii) in 2020, there was other income from DC Bead business termination compensation from Boston Scientific of RMB51.4 million while none was in 2021.

Our other expenses decreased to RMB16.8 million for the year ended December 31, 2021 from RMB75.2 million for the last year, resulted from the decrease of amortization of intangible assets in relation to Zometa. As we gradually completed conversion of distributor from Novartis to SciClone Jiangsu in 2021, we recognized partial amortization in the cost of revenue corresponding to our product revenue of Zometa, rather than full amount in other expenses.

Other Gains, Net

We had net other gains of RMB19.1 million for the year ended December 31, 2021, compared to net other gains of RMB28.5 million for the last year, primarily due to a decrease of RMB17.2 million in net foreign exchange gains resulting from fluctuations in the value of USD against RMB in 2021.

Operating Profit

As a result of the foregoing, our operating profit was RMB1,058.1 million in 2021, compared to an operating profit of RMB834.9 million for the last year.

Finance Costs, Net

We had net finance costs of RMB32.2 million in 2021, compared to a net finance cost of RMB18.1 million for the last year, primarily due to an increase of RMB10.8 million in interest expenses on borrowings from China Minsheng Banking Corp., Ltd. Hong Kong Branch in June 2020.

Income Tax Expenses

Our income tax expense increased to RMB102.5 million in 2021 from the income tax expenses of RMB63.1 million for the last year, which was primarily due to the increase in our profit before income tax during the year.

Profit for the Year

As a result of the foregoing, our profit for the year was RMB923.4 million in 2021, compared to the profit of RMB753.7 million for the last year.

Other Financial Information

Capital Structure

The Company continued to maintain a healthy and sound financial position. Our total assets grew to RMB4,062.7 million as of December 31, 2021 from RMB2,882.6 million as of December 31, 2020, whilst our total liabilities decreased to RMB1,745.3 million as of December 31, 2021 from RMB2,570.8 million as of December 31, 2020.

Liquidity, Financial Resources, and Gearing

We have historically funded our cash requirements principally from cash generated from operations, and to a lesser extent, equity and debt financing. We adopt prudent treasury policies in cash and financial management. To achieve better risk control and minimize cost of funds, our treasury activities are centralized. Cash is generally placed in short-term deposits mostly denominated in HKD. Our liquidity and financing requirements are reviewed regularly. We will consider new financing while maintaining an appropriate level of gearing in anticipation of new investments or maturity of bank loans.

As of December 31, 2021, we had cash and cash equivalents of RMB2,127.5 million, which were predominantly denominated in HKD. Going forward, we believe that our liquidity requirements will be satisfied by using a combination of cash generated from operating activities, the net proceeds received from the global offering of the Company and other funds raised from the capital markets from time to time.

As of December 31, 2021, we had no unutilized banking facilities. Our total borrowings were approximately RMB1,144.7 million as of December 31, 2021, all of which was denominated in USD. The following table sets forth further details of our banking borrowings as of December 31, 2021:

	<i>RMB million</i>	<i>Interest rate</i>
Secured	<u>1,144.7</u>	<u>LIBOR plus 2.3%</u>
Total	<u>1,144.7</u>	<u>NA</u>

As of December 31, 2021, we had a gearing ratio (total liabilities over total assets) of 43.0% (89.2% as of December 31, 2020).

Contingent Liabilities

As of December 31, 2021, we did not have any material contingent liabilities.

Capital Expenditure

Our capital expenditures principally comprise expenditures for purchases of property and equipment relating to office use and purchase of intangible assets. Our capital expenditures changed to RMB190.8 million for the year ended December 31, 2021 from RMB469.4 million for the last year. We plan to fund our planned capital expenditures using cash generated from operations and the net proceeds from the global offering of the Company.

Material Acquisitions and Future Plans for Major Investments

The Company did not conduct any material acquisition or investment during the year ended December 31, 2021.

Significant Investments Held

The Group continues to give regard to prudent capital management and liquidity risk management in its investment strategy, and follow stringent procedures to evaluate and approve investment projects. To decide whether to invest in certain acquisition and investment projects, the Company will mainly consider the assessment of the strategic impact and net present value of the project. As of December 31, 2021, the Group held 531,438 shares in Zentalis Pharmaceuticals, Inc. (NASDAQ: ZNTL, the “**Zentalis**”) (the “**Investment**”), representing approximately 1.3% of the issued and outstanding shares of Zentalis according to the public information. Zentalis is a clinical-stage biopharmaceutical company focusing on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. The Group made the investment in December 2014 with the investment cost as the nominal value of these shares and Zentalis became listed on NASDAQ in April 2020. As of December 31, 2021, the fair value of the Investment was approximately RMB284.8 million, representing approximately 7.0% of the total asset of the Group (December 31, 2020: 6.3%). The Group did not receive any dividend from Zentalis during the year of 2021. Save as disclosed above, the Group did not hold any significant investments for the year ended December 31, 2021.

Foreign Exchange Risk Management

Our subsidiaries operate in Cayman Islands, Mainland China and Hong Kong, and they are exposed to foreign exchange risk arising from currency exposure, primarily with respect to RMB. Foreign exchange risk primarily arises from recognized assets and liabilities in our subsidiaries in Cayman Islands when receiving or to receive foreign currencies from, or paying or to pay foreign currencies to business partners. We manage foreign exchange risk by performing regular reviews of our foreign exchange exposures and try to minimize these exposures through natural hedges, wherever possible, and may enter into forward foreign exchange contracts, when necessary. We did not enter into any forward contract or other financial instruments to hedge our exposure to foreign currency risk in 2021.

Employees and Remuneration Policy

As of December 31, 2021, we had approximately 890 full-time employees, most of whom were based in Mainland China, with the remainder in Hong Kong, United States, Italy, and the Cayman Islands.

Committed to establishing a competitive, fair remuneration and benefits system, we continually refine our remuneration and incentive policies in order to ensure that our employees receive competitive remuneration packages. As required under the PRC regulations, we participate in housing fund and various employee social security plan that are organized by applicable local municipal and provincial governments. We also purchase commercial health and accidental insurance for our employees. We also provide regular and specialized trainings tailored to the needs of our employees in different departments, so that our employees may stay up to date with the latest industrial developments and technological advancements. In order to incentivize our employees, we have granted and planned to continue to grant share-based incentive awards to our employees in the future to incentivize their contributions to our growth and development.

EVENTS AFTER THE REPORTING PERIOD

Save as disclosed above, there are no important events that have occurred after the end of the Reporting Period and up to the date of this announcement.

OTHER INFORMATION

Final Dividend

The Board has recommended a final dividend of HKD0.35 per share for the year ended December 31, 2021 (2020: nil).

Subject to the approval of the Shareholders at the forthcoming annual general meeting of the Company (“AGM”), the proposed final dividend will be payable on June 22, 2022 to Shareholders whose names appear on the register of members of the Company on June 2, 2022.

Use of Proceed

The Shares of the Company were listed on the Main Board of the Stock Exchange on the Listing Date with net proceeds received by the Company from the global offering in the amount of approximately HK\$2,083.6 million after deducting underwriting commissions and all related expenses.

The net proceeds have been utilized in accordance with the purposes set out in the Prospectus and approximately HK\$1,439.2 million remained unutilized up to December 31, 2021. The table below sets out the planned applications of the net proceeds and actual usage as of December 31, 2021:

Intended use of net proceeds	Allocation of net proceeds	Amount of net Proceeds utilized as of December 31, 2021 <i>HK\$ in million</i>	Balance of net Proceeds as of December 31, 2021 <i>HK\$ in million</i>
Investment in potential acquisition of new drug candidates	30%	15.6	609.5
Repayment of existing debts	28%	583.4	—
Funds to the development and commercialization of our clinical-stage product candidates	26%	9.2	532.5
Investment in recruitment and employee expansion	10%	28.2	180.2
Funds to ongoing clinical studies for additional clinical adoptions of our marketed product portfolio	6%	8.0	117.0
	<u>100%</u>	<u>644.4</u>	<u>1,439.2</u>

Save as disclosed above, since the Listing Date, the Group has not utilized any other portion of the net proceeds. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus, and the Company will gradually utilize the residual amount of the net proceeds in accordance with such intended purposes as stated in the Prospectus and expect to fully utilize the net proceeds by December 31, 2024. The expected timeline is based on the best estimation of future market conditions and business operations made by the Company, and remains subject to change based on current and future development of market conditions and actual business needs.

Compliance with Corporate Governance Code

The Company is dedicated to maintaining and ensuring high standards of corporate governance practices and the corporate governance principles of the Company are adopted in the interest of the Company and its Shareholders.

The Company has complied with all the applicable code provisions of the CG Code and adopted most of the best practices set out therein for the period from the Listing Date to December 31, 2021. As the Shares were listed on the Stock Exchange on the Listing Date, the CG Code has been applicable to the Company with effect from the Listing Date.

Model Code for Securities Transactions by Directors

The Company has adopted the Model Code as its code of conduct for directors' securities transactions. Having made specific enquiry with the Directors, all of the Directors confirmed that they have complied with the required standard as set out in the Model Code for the period from the Listing Date to December 31, 2021.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor its subsidiaries has purchased, sold or redeemed any of the Company's listed securities for the period from the Listing Date to December 31, 2021.

Review of Annual Results by the Audit Committee

The Audit Committee consists of three members, namely Ms. Wendy Hayes, Mr. Gu Alex Yushao, independent non-executive Directors, and Ms. Li Quan, non-executive Director. Ms. Wendy Hayes currently serves as the chairwoman of the Audit Committee. The Audit Committee, together with management and the Auditor, have reviewed the annual financial results of the Group for the year ended December 31, 2021.

Annual General Meeting

The AGM will be held on Thursday, May 19, 2022. A notice convening the AGM will be published and dispatched to the Shareholders in the manner required by the Listing Rules in due course.

Closure of Register of Members

In order to ascertain the Shareholders' entitlements to attend and vote at the AGM, the register of members of the Company will be closed from Monday, May 16, 2022 to Thursday, May 19, 2022, both days inclusive, during which period no transfer of Shares will be registered. All Share transfer documents accompanied by the relevant share certificates must be lodged with the Company's branch share registrar and transfer office in Hong Kong, Tricor Investor Services Limited, at Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong not later than 4:30 p.m. on Friday, May 13, 2022.

In order to ascertain the Shareholders' entitlement to the proposed final dividend, the register of members of the Company will be closed from Tuesday, May 31, 2022 to Thursday, June 2, 2022, both days inclusive, during which period no transfer of Shares will be registered. All Share transfer documents accompanied by the relevant share certificates must be lodged with the Company's branch share registrar and transfer office in Hong Kong, Tricor Investor Services Limited, at Level 54, Hopewell Centre, 183 Queen's Road East, Hong Kong not later than 4:30 p.m. on Monday, May 30, 2022.

Publication of the Annual Results and Annual Report

This annual results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.sciclone.com), and the 2021 annual report containing all the information required by the Listing Rules will be published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.sciclone.com) and will be dispatched to the Shareholders in due course.

DEFINITION

In this announcement, the following expressions shall have the following meanings unless the context requires otherwise:

“Auditor”	PricewaterhouseCoopers
“Audit Committee”	the audit committee of the Board
“Board”	the board of Directors of the Company
“China” or “PRC”	the People’s Republic of China excluding for the purpose of this announcement, Hong Kong, Macau and Taiwan
“CMO”	contract manufacturing organization serving other companies in the pharmaceutical industry on a contract basis to provide drug manufacturing service
“CNS”	central nervous system
“Company”	SciClone Pharmaceuticals (Holdings) Limited, an exempted company incorporated in the Cayman Islands with limited liability on May 13, 2020
“CG Code”	code on corporate governance practices contained in Appendix 14 to the Listing Rules
“CRF”	cancer-related fatigue
“Director(s)”	the director(s) of the Company
“DTP pharmacies”	direct-to-patient pharmacies, which refer to pharmacies that directly provide valuable professional services patients. When patients receive doctor prescriptions from the hospitals, DTP pharmacies deliver the drugs to the patients based on their prescriptions at the time and location of patients’ choices
“Group”	collectively, the Company and its subsidiaries
“HABP/VABP”	hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia
“HCC”	hepatocellular carcinoma
“HK\$”, “HKD” and “cents”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC

“Listing”	the listing of our Shares on the Main Board of the Stock Exchange
“Listing Date”	March 3, 2021, the date on which the Shares were listed on the Stock Exchange
“Listing Rules”	The Rules Governing the Listing of Securities on the Main Board of the Stock Exchange
“Model Code”	the model code for securities transactions by directors of listed issuers as set out in Appendix 10 to the Listing Rules
“Prospectus”	the prospectus of the Company dated February 19, 2021
“Reporting Period”	the one year period from January 1, 2021 to December 31, 2021
“RMB”	Renminbi, the lawful currency of the PRC
“U.S.”	the United States of America
“Share(s)”	ordinary share(s) of US\$0.00005 each in the share capital of the Company
“Shareholder(s)”	the shareholder(s) of the Company
“SMDC”	small molecule drug conjugate
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary(ies)”	has the meaning ascribed to it under the Listing Rules
“TACE”	transarterial chemoembolization
“USD”	the lawful currency of the United States of America
“%”	per cent

APPRECIATION

On behalf of the Board, I would like to express my gratitude to our shareholders, management team, employees and business partners for their continuous trust, support and dedication to the Group.

By Order of the Board
SciClone Pharmaceuticals (Holdings) Limited
ZHAO Hong
*Executive Director, Chief Executive Officer and
President*

Hong Kong, March 24, 2022

As at the date of this announcement, the Board comprises Mr. Zhao Hong as executive Director, Mr. Li Zhenfu, Dr. Daniel Luzius Vasella, Ms. Lin Shirley Yi-Hsien, Ms. Li Quan, Mr. Shi Cen and Ms. Wang Haixia as non-executive Directors, and Dr. Liu Guoen, Dr. Chen Ping, Mr. Gu Alex Yushao and Ms. Wendy Hayes as independent non-executive Directors.