CSPC Pharmaceutical (1093 HK)

Innovative platforms to drive future growth

- **Sales of legacy products to remain stable**. CSPC has nurtured market-leading products in nervous system, oncology, anti-infective and cardiovascular disease, etc. NBP, Duomeisu, Jinyouli, Keaili, and Xuanning contribute to most of the Company's product sales. NBP recorded sales growth of 10.8% YoY in 1Q23, while pressures remain on the future sales of NBP upon the launch of generics and NBP's inclusion in centralized procurement, which we think will take time. We expect the sales of NBP to remain stable over the next two years. Jinyouli won the tender at the volume-based procurement of Guangdong Alliance in 2022, while CSPC is expanding the coverage in prefecture-level markets to boost the drug's sales. The sales of Keaili may be under pressure due to the full implementation of the new VBP prices across the nation in 2023, while a new version product (fast-dissolving paclitaxel nanoparticles) is currently in Ph3 development. Overall, we expect the sales of the legacy products to remain largely stable over the next two years.
- **New products to ramp up fast.** Already approved for PTCL, Duoenda, as a broad-spectrum anti-tumor nanodrug, has the potential to treat various types of cancers. A Ph3 trial of Duoenda for 2L NPC is ongoing. We expect Duoenda to enter NRDL in 2024. Anfulike is the main lipid-based amphotericin B with obvious safety advantages for treating invasive fungal infection, which will replace current conventional amphotericin B. CSPC is broadening the hospital coverage for the drug. Additionally, the NDA of amphotericin B liposome is under CDE review, which will have a strong sales channel synergy with Anfulike. Mingfule, a 3rd-generation thrombolytic drug, has filed sNDA for thrombolytic treatment in acute ischemic stroke. We see a strong synergy between Mingfule and NBP for the treatment of ischemic stroke, which will drive the sales of both products, upon approval.
- **Well-verified R&D platforms to drive product expansion.** CSPC has 110+ innovative drug projects under development, including large molecule, small molecule and new formulation drugs, with 50+ to be approved within six years. CSPC has developed eight advanced R&D platforms. The Nano-formulation platform is well-verified with multiple blockbuster drugs approved. The mRNA platform maintains a leading position in China with COVID-19 mRNA vaccine being the first to obtain EUA approval in China. CSPC is able to complete the mRNA synthesis internally, especially the 5'-capping step, and to encapsulate the mRNA-loaded LNPs internally without patent conflicts, lowering the vaccine production costs to a large extent. About the ADC platform, DP303c (HER2 ADC) has entered into Ph3 studies, and two early-stage assets (Claudin18.2 ADC and Nectin-4 ADC) have achieved global out-licensing.
- **Maintain BUY with TP of HK$8.16**. With the fast ramp-up of new products and stable sales of legacy products, we expect CSPC's revenue to grow 2.5% / 10.1%/ 10.3% YoY in FY23E/ 24E/ 25E and attributable net profit to grow 2.5%/ 10.3%/ 10.3% YoY in FY23E/ 24E/ 25E, respectively. We derive our DCF-based TP of HK$8.16 (WACC 11.85%, terminal growth 2.0%).

Earnings Summary

(YE 31 Dec)	FY21A	FY22A	FY23E	FY24E	FY25E
Revenue (RMB mn)	27,867	30,937	31,715	34,903	38,511
YoY growth (%)	11.7	11.0	2.5	10.1	10.3
Attributable net profit (RMB mn)	5,605	6,091	6,243	6,889	7,596
YoY growth (%)	8.6	8.7`	2.5	10.3	10.3
EPS (Reported) (RMB)	0.47	0.51	0.52	0.58	0.64
P/E (x)	16.8	14.2	9.9	9.0	8.2
Net gearing (%)	(40.9)	(44.1)	(52.9)	(59.4)	(64.9)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	**HK$8.16**
(Previous TP	HK$8.08)
Up/Downside	**46.2%**
Current Price	**HK$5.58**

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Stock Data

Mkt Cap (HK$ mn)	66,498.0
Avg 3 mths t/o (HK$ mn)	232.3
52w High/Low (HK$)	10.18/5.29
Total Issued Shares (mn)	11,917.2

Source: FactSet

Shareholding Structure

Massive Giant Group Ltd	10.2%
Cai Dongchen	9.9%

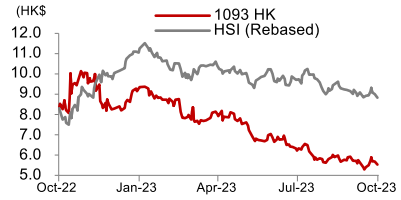
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	-4.3%	-0.3%
3-mth	-11.3%	-2.2%
6-mth	-29.5%	-16.3%

Source: FactSet

12-mth Price Performance



Source: FactSet

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Sales of legacy products to largely remain stable

With professional sales force of 10,000+, covering more than 35,000 medical institutions in China, CSPC has developed strong commercialization capabilities. The sales team has successfully marketed core products such as NBP, Duomeisu, Jinyouli, Keaili, Xuanning, etc, which contribute to the majority of the Company's product sales.

In FY22, CSPC reported FY22 revenue of RMB30.94bn (+11.0% YoY) and attributable net profit of RMB6.09bn (+8.7% YoY). The FY22 sales of finished drugs increased 8.1% YoY to RMB22.68bn, accounting for 73.3% of the total revenue. In 1H23, the Company recorded revenue of RMB16.08bn, with the sales from finished drugs increased 5.2% YoY to RMB12.93bn, among which nervous system, oncology, anti-infective and cardiovascular disease related products contributed the most to sales.

Figure 1: 1H23 revenue breakdown

Revenue by product category
Unit: RMB MM

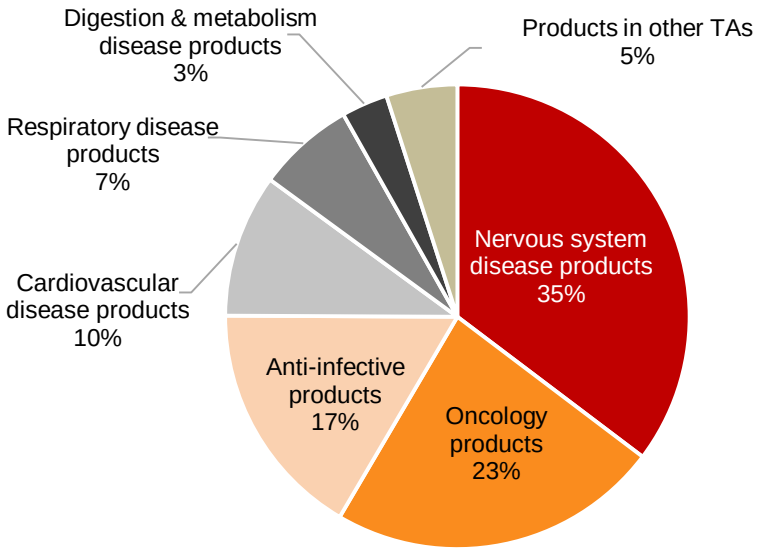
	1H2023	1H2022	Change
Finished drugs	12,934	12,293	+5.2%
Bulk vitamin C	1,040	1,399	-25.7%
Bulk antibiotics	930	781	+19.1%
Functional Food and Other Business	1,177	1,137	+3.5%

Finished drug revenue
Unit: RMB MM

	1H2023	1H2022	Change
Nervous system disease products	4,553	3,874	+17.5%
Oncology products	2,988	4,035	-26.0%
Anti-infective products	2,143	1,753	+22.3%
Cardiovascular disease products	1,287	1,519	-15.3%
Respiratory disease products	874	274	+219.2%
Digestion & metabolism disease products	416	362	+15.1%
Products in other TAs	638	477	+33.9%
Licence fee income	35	-	-

Source: Company data, CMBIGM

Figure 2: Finished drug revenue breakdown in 1H23



Source: Company data, CMBIGM

Figure 3: Major commercial products

Brand name	Generic name	Dosage form	Therapeutic area	Indications	Initial year of launch	NRDL	Impacted by centralized procurement
NBP (恩必普)	Butyphthalide (丁苯酞)	capsule, injection	Nervous system	acute ischemic stroke	2002	2023.03 - 2024.12	N
Duomeisu (多美素)	Doxorubicin hydrochloride liposome (盐酸多柔比星脂质体)	injection	Oncology	lymphoma, multiple myeloma, ovarian cancer, breast cancer and other malignant tumors	2011	N	N
Jinyouli (津优力)	PEG-rhGCSF (聚乙二醇重组人粒细胞刺激因子)	injection	Oncology	prevention of leucopenia induced by chemotherapy and infection induced by febrile neutropenia	2012	2022.01 - 2023.12	Y
Keaili (克艾力)	Paclitaxel (albumin-bound) (白蛋白结合型紫杉醇)	freeze-dried powder for injection	Oncology	breast cancer	2018	2023.03 - 2024.12	Y
Xuanning (玄宁)	Levamlodipine maleate (马来酸左旋氨氯地平)	tablet	Cardio-vascular	hypertension, chronic stable angina and variant angina	2013	Y	N

Source: Company data, CMBIGM

NBP, sales to remain stable given limited competition in the coming two years

NBP (butylphalide) is a Class 1 new chemical drug in China and a patent-protected product mainly used for the treatment of acute ischemic stroke. It is recommended in the guidelines of various authoritative organizations such as the Chinese Medical Association, the Chinese Stroke Association, etc.

In 2022, NBP maintained stable sales growth with annual sales reaching around RMB7.0bn. NBP injection accounted for around 2/3 of NBP sales and the remaining 1/3 sales were from the capsule formulation. In 1H23, CSPC's nervous system disease products recorded a robust YoY increase of 17.5%, mainly driven by the sales of NBP. The sales of NBP capsule were mainly from the OTC channel, while the sales growth was mainly driven by the extending duration of treatment (DoT). NBP capsule was added to the NRDL in 2009, while NBP injection has been included in the NRDL since 2017. Due to the changes in the NRDL policy, NBP injection/capsule went through price negotiations in 2020 and successfully renewed the NRDL in Jan 2023. During the latest NRDL price negotiation, NBP capsule maintained flattish pricing while NBP injection experienced a moderate 16% price cut. The increase in sales volume of the drug will offset the price cut, in our view. We think the pricing of NBP will maintain largely stable until any changes in the competition environment.

CSPC is developing new indications to bring new growth opportunities for NBP. Currently, CSPC is conducting a Ph3 trial of NBP capsule in vascular dementia (CTR20190809/NCT03804229) and a Ph2 trial of NBP capsule in paclitaxel-induced peripheral neuropathy (CTR20220493). The Ph3 trial in vascular dementia targets to enroll 700 subjects with the enrollment expected to be completed by end-2023.

The patent of NBP capsule will expire in Dec 2023, while the patent of NBP injection already expired in Jun 2022. However, we believe NBP is able to maintain its market-leading position over the coming 2-3 years given its strong brand and mature distribution network. There is no reference listed drug (参比制剂) for generic NBP. In Oct 2023, the CDE issued the guidance on the "Generic Research of Varieties without Reference Listed Drug (link). According to the document, strict randomized controlled clinical trials are required to verify the clinical value of the generics, which could be time and capital consuming (“应根据药物适应症特点和常用有效治疗手段合理选择对照，开展随机对照试验”).

At the time, several potential NBP generic drug candidates are under clinical trial studies. The ANDA of generic NBP injection by Nanjing Yoko (CXHS2000011) was rejected by CDE in 2021. Livzon filed ANDA of generic NBP injection in 2016, while the review process is not active. Additionally, several pharmaceutical companies are developing NBP generics or modified new drugs, while their registration process may be impacted by the above-mentioned new rules of the CDE. Given the current development landscape and policy status, we think it is unlikely to see potential NBP generic approvals by 2025. As such, we expect CSPC's NBP to continue to enjoy its exclusive market position in the foreseeable future.

Figure 4: Development of NBP generics / modified new drugs

Drug dosage form	Company	Innovation type	Drug category	First NDA/ANDA	Application No.	Review result	Date of approval/ rejection
Butylphthalide injection	Nanjing Yoko Pharma	Generics	2.2	2020-05-23	CXHS2000011	**Marketing application rejected**	2021-12-23
Butylphthalide injection (large volume)	Livzon	Generics	4	2016-12-19 (not active)	CYHS1600199	BE study completed in Jan 2021	
Butylphthalide soft capsule	Huahai Pharma	Generics	4			BE study completed in Mar 2023	
Butylphthalide injection (large volume)	Huahai Pharma	Generics	4			BE study ongoing (started in Aug 2023)	
Butylphthalide soft capsule	Zhejiang Mei Di Shen	Generics	4			BE study ongoing	
Butylphthalide injection (large volume)	Zhejiang Mei Di Shen	Generics	4			BE study completed in Jan 2022	
Butylphthalide injection (large volume)	Fujian Baonuo	Generics	4			BE study completed in Jan 2022	
Butylphthalide injection	Beijing Hai Yi	Modified new drug	2.2		CXHL2101422	Clinical trial approved	2021-11-03
Butylphthalide injection	Hebei Saipu Ruisi	Modified new drug	2.2		CXHL2200186	Clinical trial approved	2022-06-09
Butylphthalide injection	Jilin Qijian Biotech	Modified new drug	2.2		CXHL2101684	Clinical trial approved	2022-02-15
Butylphthalide injection	Renhe Yikang	Modified new drug	2.2		CXHL2200153	Clinical trial approved	2022-05-27
Butylphthalide injection	Sichuan Huiyu Pharma	Genetics	2.2		CXHL2101404	Clinical trial approved	2021-11-02

Source: Pharmcube, CMBIGM. Note: data retrieved as of Sep 2023

Duomeisu, a leading brand of liposomal doxorubicin in China

Duomeisu (doxorubicin hydrochloride liposome injection) is recommended by the US NCCN and China CSCO guidelines for the first-line treatment of lymphoma, ovarian cancer, relapsed or metastatic breast cancer, soft tissue sarcoma and AIDS-related Kaposi's sarcoma (AIDS-KS). Duomeisu is officially approved by the CDE for treatment of AIDS-KS. Duomeisu is a leading brand of liposomal doxorubicin in China and was the first to pass the consistency evaluation (一致性评价) in May 2021.

Currently, five doxorubicin hydrochloride liposome drugs have been approved in China, and four of which have passed the consistency evaluation, including Duomeisu, and generics from Jiminkexin Medicine (Changzhou Jinyuan), Zhejiang Zhida Pharma and Zhejiang Sundoc. Several generic drugs are under review as well. Thanks to CSPC's strong distribution network, Duomeisu occupies the majority of China's liposomal doxorubicin market with market share of roughly 70%. To date, six pharmaceutical companies have filed ANDAs for doxorubicin hydrochloride liposome generics, indicating potential intensifying competition in this field, in our view.

Figure 5: Landscape of doxorubicin hydrochloride liposome generics in China

Company name	Marketing status	Consistency evaluation	Time of product launch / ANDA filing
Zhejiang Sundoc	Approved	Passed	2023
Zhejiang Zhida Pharma	Approved	Passed	2023
Jiminkexin Medicine (Changzhou Jinyuan)	Approved	Passed	2012
CSPC Pharma	Approved	Passed	2011
Fudan-Zhangjiang	Approved	-	2008
Sun Pharma/CMS	ANDA filed	-	2021-01-11
Qilu Pharma	ANDA filed	-	2023-01-20
Hisun Pharma	ANDA filed	-	2022-04-29
Luye Pharma	ANDA filed	-	2023-06-02
Taxus Pharma	ANDA filed	-	2022-09-19
Dr. Reddy's	ANDA filed	-	2022-01-30

Source: Pharmcube, CMBIGM. Note: as of Oct 2023

Duomeisu is not included in the NRDL yet while it is covered by several commercial insurance programs initiated by regional governments (惠民保). Affected by the COVID-19 control measures in China and the adjustment of reimbursement policy of provincial basic medical insurance lists in Liaoning and Hunan, sales of Duomeisu decreased in 2022. The Company aims to expand the market potential of Duomeisu in lower-tier cities and counties.

Jinyouli, to explore mass market opportunities

Jinyouli (PEG-rhG-CSF injection) is the first long-acting white blood cell booster drug developed in China. It is used to prevent and treat incidence of infection and pyrexia due to low neutrophil count in patients receiving chemotherapy, thus ensuring the administration of standardized dosage of chemotherapy. PEG-rhG-CSF is widely recommended by domestic and foreign guidelines.

Currently, short-acting white blood cell booster drugs still have significant market share in China (roughly 50%). CSPC targets to further promote the use of long-acting white blood cell booster drugs in mass markets.

A couple of long-acting white blood cell booster drugs have been approved in China, including Jinyouli, Xinruibai, Aiduo, Shenlida, etc. In 2022, PEG-rhG-CSF was included in the centralized procurement of Guangdong Alliance of 11 provinces, while Jinyouli successfully won the tender with a price cut of 53%. Given Jinyouli previously offers buy one get one free PAP to patients in certain regions, the actual price decline was not very dramatic. We expect Jinyouli to deliver steady growth in coming years.

Figure 6: Landscape of long-acting white blood cell booster drugs in China

Drug name	Drug name (Chinese)	Brand name	Company	Type of drug	Year of launch	NRDL
Pegfilgrastim	聚乙二醇重组人粒细胞刺激因子	津优力	CSPC Pharma	Innovative drug	2011	Yes (Class B)
Pegfilgrastim	聚乙二醇重组人粒细胞刺激因子	新瑞白	Qilu Pharma	Biosimilars	2015	Yes (Class B)
Mecapegfilgrastim	硫培非格司亭	艾多	Hengrui Medicine	Innovative drug	2018	Yes (Class B)
Pegfilgrastim	聚乙二醇重组人粒细胞刺激因子	申力达	Lunan Pharma	Biosimilars	2021	Yes (Class B)
Efbemalenograstim alfa	艾贝格司亭α	亿立舒	Evive Biopharma	Innovative drug	2023	None
YPEG-rhG-CSF	拓培非格司亭	珮金	Amoytop Biotech	Innovative drug	2023	None
Pegfilgrastim	聚乙二醇重组人粒细胞刺激因子	-	SL Pharm	Biosimilars	NDA in 2021.12	-
Pegfilgrastim	聚乙二醇重组人粒细胞刺激因子	-	Jiuyuan Gene	Biosimilars	NDA in 2023.05	-

Source: Pharmcube, CMBIGM. Note: as of Oct 2023

Keaili, sales under pressure due to VBP, while 2nd-generation product is in Ph3 study

Keaili (albumin-bound paclitaxel) is the first-to-market generic of new generation paclitaxel chemotherapy drug approved in 2018 in China which has passed the consistency evaluation. It is widely recommended by domestic and foreign guidelines for breast cancer, lung cancer, gastric cancer and gynaecological tumours.

In 2020, Keaili experienced a 70% price cut to RMB747 per 100mg during the National VBP. The original drug, ABRAXANE from Celgene (acquired by BMS), withdrew from China's market in 2020 due to supply issues. Thus, CSPC and Hengrui have dominated China's albumin-bound paclitaxel market since 2020. Nevertheless, given intensified competition with new comers such as Qilu Pharma, Kelun Pharma, Hisun Pharma and Jiangsu Kanghe, prices of Keaili have reduced significantly since 2022 due to VBP renewal.

In 2022, Keaili has completed contract renewal of the volume-based procurement of Henan Alliance of 13 provinces with a significant price reduction of 80% to RMB148 per 100mg, leading to sales revenue decline from 2022. Expecting the VBP renewal price to be gradually implemented across the country in 2023, sales of Keaili will continue to be under further pressure, in our view.

Figure 7: Approved albumin-bound paclitaxel in China

Company	Type of drug	Year of launch in China	Consistency evaluation
Jiangsu Kanghe	Generic	2022	Passed
Hisun Pharma	Generic	2021	Passed
Kelun Pharma	Generic	2020	Passed
Qilu Pharma	Generic	2019	Passed
Hengrui Medicine	Generic	2018	Passed
CSPC Pharma	Generic	2018	Passed
Celgene (BMS)	Innovative drug	2008 (importation terminated in 2020)	N/A

Source: Pharmcube, CMBIGM. Note: as of Oct 2023.

CSPC is developing a new version of paclitaxel, the fast dissolving paclitaxel nanoparticles. The product has lower proportion of albumin than Keaili, leading to fast dissolving characteristic, reduced immunogenicity, and better safety profile. The product is a class 2 modified new drug currently at pivotal Ph3 study. We expect this new version of paclitaxel to enjoy favorable pricing compared to Keaili and will be able to take considerable market share from the traditional paclitaxel and albumin-bound paclitaxel.

New products to ramp up fast

Multiple new products of CSPC have been approved in recent years, which could offset the sales pressure of legacy products. Among these products, Duoenda, Anfulike, and Mingfule are potential blockbusters.

Figure 8: Major newly approved products

Brand name	Generic name	Therapeutic area	Indications	Initial year of launch	NRDL
Duoenda (多恩达)	Duoenda (mitoxantrone hydrochloride liposome) (盐酸米托蒽醌脂质体注射液)	Oncology	Malignant lymphoma, breast cancer and acute leukaemia	2022-01	N
Anfulike (安复利克)	Amphotericin B cholesteryl sulfate complex (两性霉素 B 胆固醇硫酸酯复合物)	Anti-infective	Invasive fungal infections, renal impairment or drug toxicity precludes the use of amphotericin B, etc	2021-03	N
Mingfule (铭复乐)	Recombinant human TNK tissue type plasminogen activator (重组人 TNK 组织型纤溶酶原激活剂)	Cardio-vascular	Relapsed/refractory peripheral T-cell lymphoma	2015-01 (Acquired by CSPC in 2022)	N

Source: Company data, CMBIGM

Duoenda, a broad-spectrum anti-tumor nanodrug

Duoenda (mitoxantrone hydrochloride liposome injection) is a self-developed, class 2, globally exclusive innovative formulation oncology nanodrug, which obtained conditional market approval in China for the treatment of relapsed/refractory peripheral T-cell lymphoma (PTCL) in Jan 2022. Duoenda was recommended by the CSCO Guidelines for Lymphoma (2022 version) for the treatment of r/r PTCL (Grade 2A) and NKT lymphoma (Grade 2B).

Duoenda is in-house developed by CSPC and is also the first mitoxantrone nanodrug launched worldwide. The product has patents authorized in more than ten countries and regions including China, the US, Europe, Japan, etc. Duoenda adopts unique drug loading and release technology to ensure the nanoparticles to be effectively enriched in tumor after administration, thereby increasing the bioavailability of the drug and leading to improvement in efficacy and safety. Duoenda can also avoid skin toxicity and infusion-related reactions which are commonly seen in nanodrugs.

According to NHL treatment guidelines, PTCL accounted for 15%-22% of NHL in China. The guideline recommended first line treatment options include CHOP, CHOEP, DA-EPOCH, etc., while for 2L treatment, tucidinostat and brentuximab vedotin are recommended. However, the outcomes of PTCL with the current available treatment options are poor, and the 5-year survival rate is only around 30%.

Clinical studies have indicated that Duoenda has a significantly better efficacy than other drugs in treating patients with r/r PTCL. In a single arm open label pivotal Ph2 trial (NCT03776279, link), 108 PTCL patients with at least one prior treatment received Duoenda and 78 patients were evaluable for efficacy. With a median follow-up period of 15.6 months, the ORR was 41.0% (CR 21.8%, PR 19.2%), mPFS was 7.5 months and the median duration of response was 11.5 months. Duoenda demonstrated improved efficacy in PFS and CR than other drugs for PTCL treatment, such as tucidinostat and pralatrexate.

Figure 9: Cross-trial comparisons of drugs for R/R PTCL treatment

	Duoenda	Tucidinostat (西达本胺)	Pralatrexate (普拉曲沙)
Patient No	78	55	71
ORR	41%	46%	52%
CR, CRu	*22%*	*11%*	*20%*
PR	*19%*	*35%*	*32%*
DoR (months)	11.5	11.5	8.7
mPFS (months)	*7.5*	5.6	4.8
mOS (months)	NA	22.8	18.0
Source	Link	Link	Link

Source: Pubmed, CMBIGM

Duoenda is a broad-spectrum anti-tumor nanodrug with potential to be used for the treatment of various type of cancers. This product is actively exploring the field of hematological tumors including T-cell lymphoma, diffuse large B-cell lymphoma, acute myeloid leukemia and multiple myeloma, and solid tumors including nasopharyngeal cancer (NPC).

The Company has initiated a Ph3 trial of Duoenda for the treatment of patients with recurrent metastatic NPC who have failed platinum-based therapy (NCT05717764). Additionally, Duoenda has also obtained clinical trial approval and orphan drug designation in the US with clinical studies in progress.

Figure 10: Clinical trials of Duoenda

NCT number	Study phase	Target indications	Regimen	Actual start date	Estimate completion date	Enroll-ment No.
NCT05717764	Phase III	NPC	Duoenda + capecitabine vs capecitabine alone	2023-02-01	2027-09-01	500
NCT04668690	Phase III	PTCL	Duoenda vs chidamide	2021-01-01	2028-12-30	190
NCT05603884	Phase II	AML	Duoenda, venetoclax, chidamide, azacitidine, cytarabine, filgrastim	2022-12-01	2025-06-30	66
NCT05100329	Phase II	pancreatic cancer	Duoenda	2021-11-01	2024-05-01	38
NCT05875428	Phase II	DLBCL	Duoenda	2023-06-01	2025-09-30	104
NCT04352413	Phase II	SCLC	Duoenda	2020-06-18	2022-01-30	81
NCT05575973	Phase II	DLBCL	Duoenda, rituximab, lenalidomide	2022-10-10	2025-10-01	55
NCT05551598	Phase II	neuromyelitis optica (NMO)	Duoenda	2022-11-15	2025-04-15	45
NCT03776279	Phase II	NKTCL, PTCL	Duoenda	2018-04-02	2020-12-30	106
NCT05345938	Phase I/II	AML	Duoenda, mitoxantrone	2022-05-30	2025-02-15	90
NCT05100303	Phase I/II	AML	Duoenda, cytarabine	2021-12-01	2023-06-01	58
NCT05522192	Phase I/II	AML	venetoclax, Duoenda, mitoxantrone	2022-07-21	2026-05-01	70
NCT05441761	Phase I/II	PTCL	gemcitabine, Duoenda, cisplatin, dexamethasone, mitoxantrone	2022-05-01	2025-05-01	60
NCT04900766	Phase I	soft tissue sarcoma (STS),osteosarcoma	Duoenda, mitoxantrone	2021-06-01	2023-06-01	50
NCT04719065	Phase I	solid tumor	Duoenda	2021-01-13	2024-04-13	90
NCT04921878	Phase I	solid tumor	Duoenda	2021-06-01	2024-06-01	104
NCT04718402	Phase I	gastric cancer	Duoenda	2021-03-30	2024-01-19	30
NCT05620862	Phase I	solid tumor,lymphoma	Duoenda	2022-10-25	2025-06-01	33
NCT04902027	Phase I	head and neck cancer	Duoenda	2021-07-01	2024-04-01	30
NCT05344742	Phase I	solid tumor	Duoenda, mitoxantrone, paclitaxel, capecitabine	2022-04-01	2025-03-01	116
NCT05299164	Phase I	aggressive non-Hodgkin's lymphoma	gemcitabine, Duoenda, vinorelbine, rituximab, mitoxantrone	2022-05-15	2024-12-31	24
NCT05458180	Phase I	PTCL	Duoenda, vincristine, prednisone, cyclophosphamide, etoposide	2022-07-07	2025-04-15	18

Source: Pharmcube, CMBIGM

At ASCO 2022 meeting, the results of a Ph1b trial of Duoenda for the treatment of platinum-refractory or platinum-resistant recurrent ovarian cancer were presented in E-poster, and the results of a Ph1b trial for the treatment of recurrent/metastatic squamous cell carcinoma of head and neck were presented online. Preliminary results indicate that Duoenda has a satisfying safety profile and observable efficacy in both indications. At ESMO 2022 meeting, the results of a “dose escalation and dose expansion study of mitoxantrone hydrochloride liposome injection in combination with pegaspargase for the treatment of extranodal NK/T-cell lymphoma (ENKTCL)” were presented. Preliminary results indicate that Duoenda in combination with pegaspargase has significant efficacy, especially for patients with primary ENKTCL, with manageable safety risks.

On the commercialization side, CSPC has newly established a haematology sales team for the promotion of Duoenda and other related products, and has now covered more than 500 hospitals. With the sales synergies with Copiktra (PI3K δ/γ dual-target inhibitor), the sales of Duoenda may ramp up rapidly, in our view. We think sales of Duoenda may reach around RMB200mn in 2023E. We also expect Duoenda to participate in the NRDL negotiation in late 2023.

Anfulike, a good althernative for the traditional type amphotericin B

Anfulike (amphotericin B cholesteryl sulfate complex for injection) was approved in Mar 2021 for the treatment of patients with invasive fungal infections who is amphotericin B intolerant or resistant. It is recommended jointly by the State Ministry of Industry and Health Care Commission as a "clinically essential, market-deficient" product.

Amphotericin B is a type of polyene antibiotic, and is a drug with the strongest antifungal activity and broadest antimicrobial spectrum for prevention and treatment of invasive fungal infections. However, there are concerns on the

clinical application of conventional type of amphotericin B due to its nephrotoxicity. Globally, three lipid-based formulations of amphotericin B have been approved, namely Amphotec, AmBisome and Abelcet, which largely reduced the incidence of nephrotoxicity, providing good alternatives for the traditional type amphotericin B.

Amphotec was initially approved in China in 2004 while the commercialization discontinued in 2011 due to manufacturing issues. Anfulike from CSPC is the first and currently only generic drug of Amphotec in China. Comparing with the conventional type of amphotericin B, Anfulike can significantly decrease nephrotoxicity and increase dosage, thus expanding the therapeutic window. AmBisome currently has dominated the global amphotericin B market for many years, while the drug was lately launched in China in May 2023. Abelcet has not been approved in China. The AmBisome generic, Fengkesong (锋克松), from Shanghai Pharma (New Asia Pharma) was approved in 2003 in China, while the sales of Fengkesong is limited. Due to the limited supply of lipid-based drugs, the current China's market of amphotericin B is still dominant by conventional amphotericin B. We foresee Anfulike to gradually take market share from traditional amphotericin B in China.

The affordability and accessibility of Anfulike has improved with its inclusion into the NRDL in Dec 2021. As the clinical use of antibiotics is strictly controlled, hospitals usually prudently renew their antibiotics list. CSPC is continuously working on broadening its hospital coverage for Anfulike, which we expect could be time-consuming. We expect Anfulike to achieve around RMB300mn sales from Anfulike in 2023.

Additionally, CSPC has filed NDA for amphotericin B liposome (a generic of AmBisome) in China for treatment of invasive fungal infection, with the approval expected in 2024. Upon approval, amphotericin B liposome will have sales synergies with Anfulike, in our view.

Mingfule, 3g- thrombolytic drug with strong synergy with NBP for ischemic stroke

Mingfule (recombinant human TNK tissue-type plasminogen activator for injection, rhTNK-tPA) is a third-generation thrombolytic drug with proprietary intellectual property. It was developed by Recomgen Biotech. CSPC acquired 51% stake in Recomgen Biotech in Feb 2022 and then increased its interest to 54.8% later. Mingfule obtained marketing approval in China in Jan 2015 for the thrombolysis treatment in patients with acute myocardial infarction within six hours of onset. The drug has been listed as a recommended thrombolytic drug in the Chinese Expert Consensus on Pre-hospital Thrombolysis, Guidelines for Rational Use of Drugs for STEMI (201902) and other authoritative guidelines.

There are currently three generations of thrombolytic drug used in clinic. The first generation of thrombolytic drugs, streptokinase and urokinase, are fibrin-unspecific agents. These drugs quickly bind with plasminogen in the plasma and the clot, which result in excess depletion of plasminogen and a high risk of intracranial hemorrhage. The second-generation agents, such as tissue plasminogen activator (tPA) and its variants (alteplase, prourokinase, etc.), have fibrin-targeting properties and are the current mainstream thrombolytic drugs, while these drugs have short half-lives. Several third-generation agents (TNK-tPA, reteplase, etc.) have been developed, which could be alternatives to the second generation drug due to improved administration convenience and better safety profile. In China, the second-generation agent alteplase is the most common thrombolytic drug in the clinic, accounting for around 70% of the market, followed by the first generation agent urokinase (15%), and the second-generation agent prourokinase (13%). There is no generic alteplase yet in China.

Mingfule is a third-generation recombinant tissue plasminogen activator (rt-PA) product, a mutant of rt-PA. Compared with conventional rt-PA thrombolytic drug products, Mingfule is safer and more effective with a longer half-life period and stronger antagonistic capability of plasminogen activator inhibitor-1 (PAI-1), enhancing the ability and specificity to combine with fibrin. Compared with conventional rt-PA products which are administered by bolus injection followed by continuous intravenous infusion for 1 hour, Mingfule can be administered by a single bolus intravenous injection within 5-10 seconds, which is convenient and allows patients to complete intravenous thrombolytic treatment in a shorter time, demonstrating significant clinical application advantages.

Apart from the treatment of acute myocardial infarction, CSPC is expanding the indications of Mingfule. In Jul 2022, Mingfule has met its predefined primary endpoint in a Ph3 clinical study (TRACE II) for the treatment of acute ischemic stroke within 4.5 hours of symptoms onset. With 1,430 subjects enrolled, the study demonstrated that Mingfule is non-inferior to alteplase in efficacy (the proportion of subjects with a mRS of 0 to 1 at 90 days, 62% vs 58%, link) and has a trend of enhancement in efficacy, while the safety profile is similar to alteplase. In Nov 2022, sNDA of Mingfule for the

thrombolytic treatment in patients with acute ischemic stroke was submitted. The approval of this indication will greatly expand the market potential of Mingfule, which will share the sales synergies with NBP.

In order to satisfy the unmet clinical needs of patients with acute ischemic stroke, the clinical study of Mingfule for the treatment of acute large-arterial occlusive stroke of longer time window (4.5-24 hours onset) has been initiated. Based on the characteristics of the mechanism of action and the existing clinical data of Mingfule, CSPC plans to continue the development of Mingfule in combination with endovascular therapy in ischemic stroke and other indications including deep vein thrombosis, pulmonary embolism, central retinal artery occlusion.

We see strong synergies between Mingfule and NBP for the treatment of ischemic stroke. Mingfule could be applied to patients with acute ischaemic stroke during the early stage of symptoms onset (within 4.5 hours of onset), while NBP injection will be used during hospital treatment, and NBP capsule could further extend the DoT after patients are discharged from hospital. We expect Mingfule, which will leverage the matured distribution channel of NBP, to achieve rapid sales ramp-up. We expect Mingfule to realize RMB300mn sales in 2023, with peak sales potential of RMB2.0-3.0bn, upon the approval of new indications.

Broad clinical-stage product pipelines

While the legacy products continue the steady sales performance and the newly approved products ramp up quickly, CSPC currently also has over 110 drug pipelines under development, including approximately 40 large molecule drugs, 40 small molecule drugs and 30 new-formulation drugs.

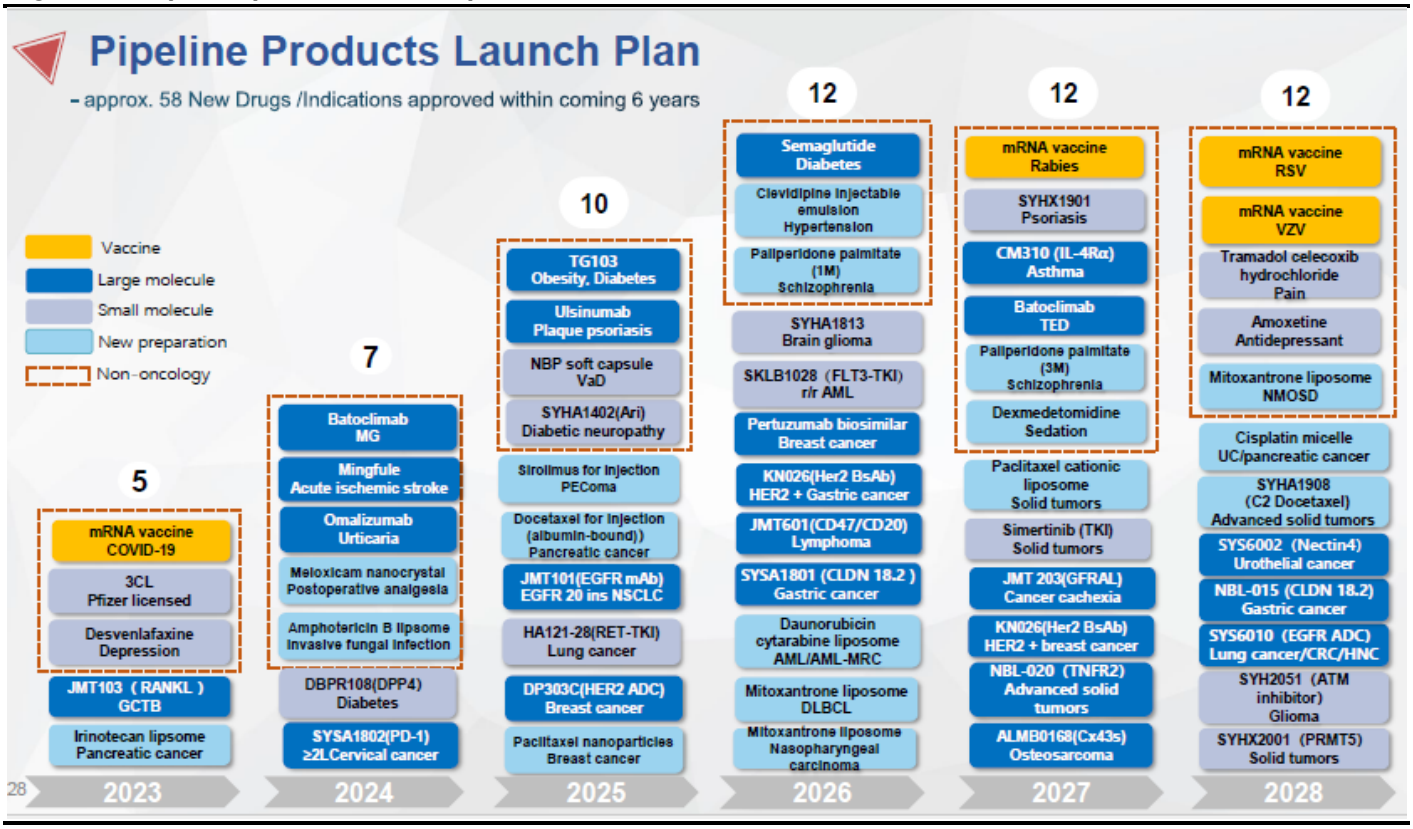
For the 40 large molecule drug candidates, JMT103 (RANKL antibody) was recently approved for GCTB in Sep 2023, and four are under NDA review, including Mingfule (rhTNK-tPA, the new indication of acute ischemic stroke to be approved in 2023), SYSA1802 (PD-1 mAb, to be approved in 2024 for 2L+ CC), batoclimab (FcRn andtibody) and omalizumab (IgE) biosimilar. In addition, CSPC has 18 clinical-stage large molecule candidates, seven of which are at pivotal trials.

For the 40 small molecule drug candidates, desvenlafaxine (generic) was approved in Jul 2023 for depression, and DBPR108 (DPP4) is under NDA review for diabetes. Additionally, 22 drug candidates are under clinical trial stage (four under Ph3/pivotal trial stage).

For the 30 new formulation drugs under development, irinotecan lipsome (generic) was recently approved for pancreatic cancer, and amphotericin B lipsome is currently under NDA review for invasive fungal infection. The Company has 11 new formulation drug candidates under clinical trials.

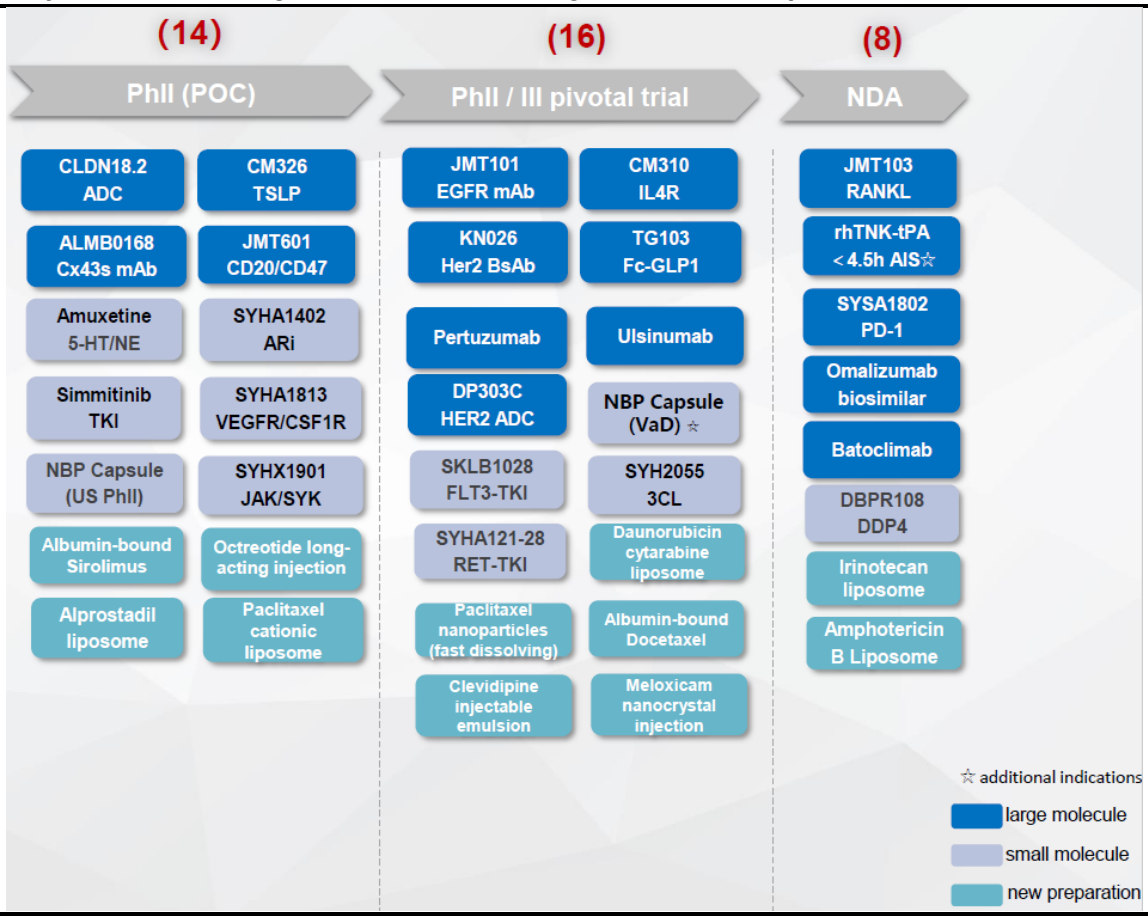
By 2028, around 58 new drugs/indications are expected to be approved, including 6 in 2023, 6 in 2024, and 10 in 2025, etc. These new products serve as the continuous revenue generation engine of CSPC.

Figure 11: Pipeline products launch plan



Source: Company data, CMBIGM. Notes: as of Aug 2023.

Figure 12: Major innovative drug candidates at late-stage clinical development



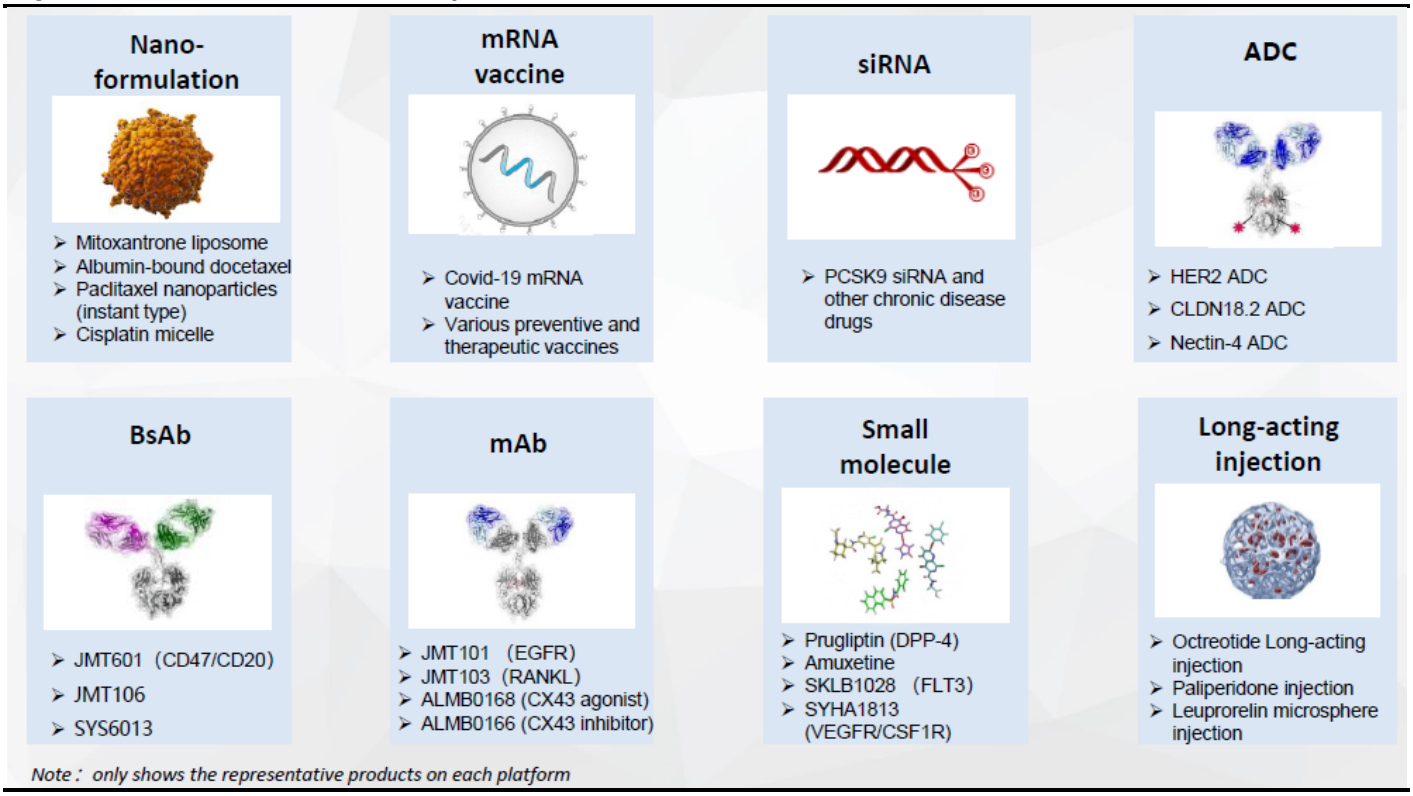
Source: Company data, CMBIGM. Note: as of Aug 2023.

Innovative platforms continue to drive the R&D progress

CSPC has built an internationalized R&D team with more than 2,000 members and five key R&D centres in Shijiazhuang, Shanghai, Beijing and the US, focusing on six key therapeutic areas of oncology, psychiatry and neurology, cardiovascular, immunology and respiratory, digestion and metabolism, and anti-infectives.

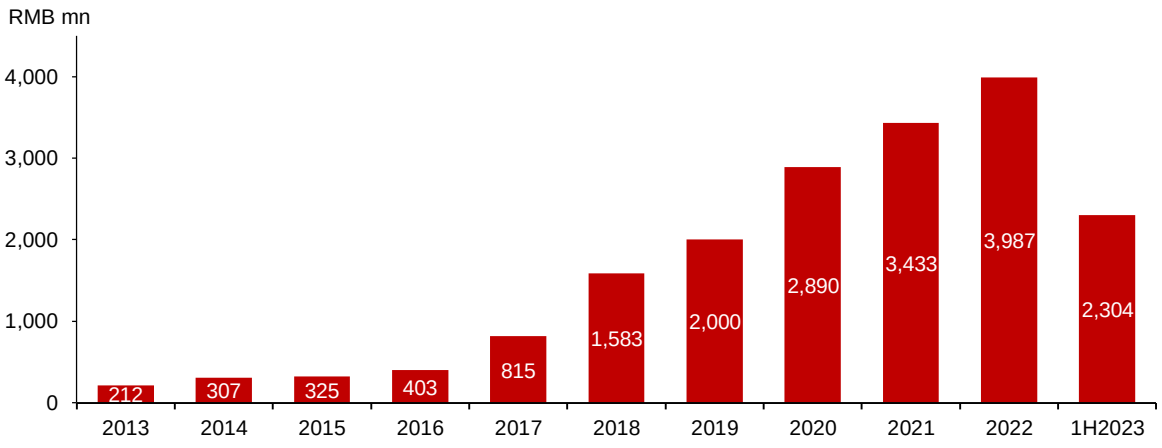
CSPC has established eight innovative R&D platforms, encompassing nano-formulation, mRNA vaccine, siRNA, ADC, BsAb, mAb, small molecule and PROTAC. The Company continues to invest in its R&D. The R&D expenses reached RMB4.0bn in FY22 and RMB2.3n in 1H23. The Company's continuous investment will provide strong support for the research and development of innovative drugs.

Figure 13: CSPC's innovative R&D platforms



Source: Company data, CMBIGM.

Figure 14: R&D spending of CSPC (2013-1H2023)



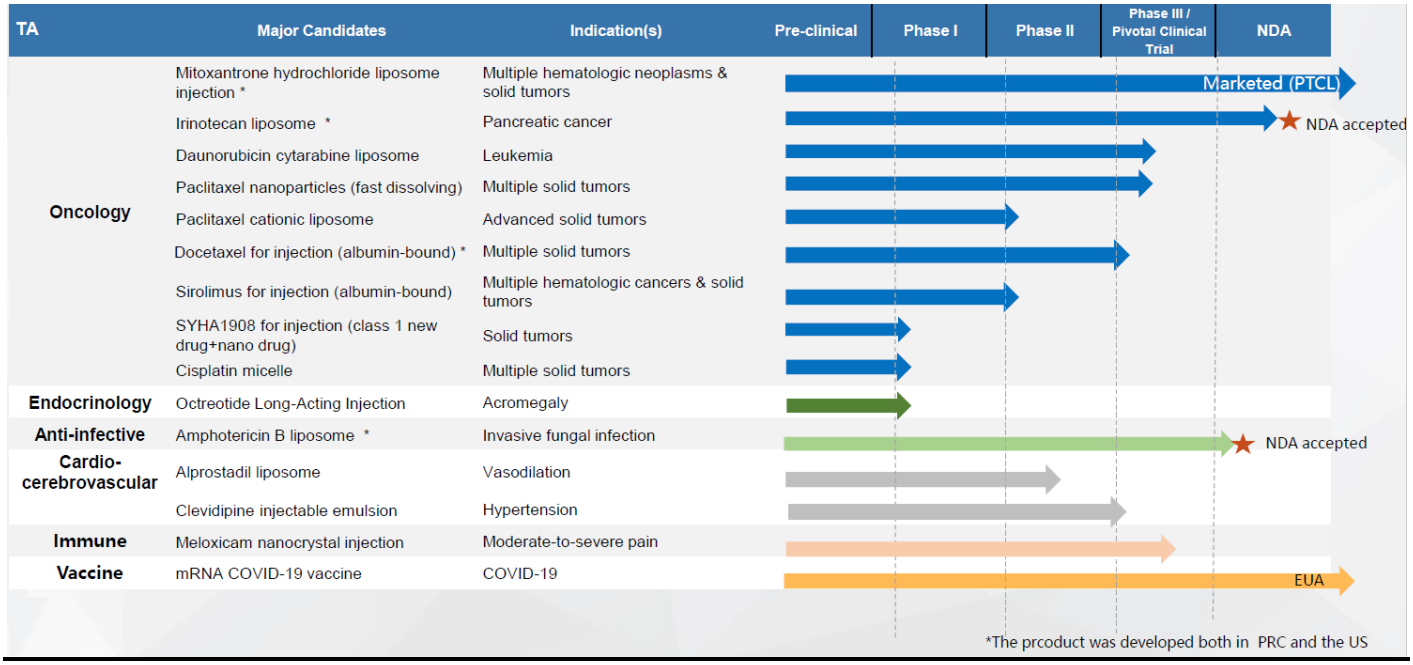
Source: Company data, CMBIGM.

Nano formulation platform, well-verified with multiple marketed nano drugs

CSPC's nano-formulation technology platform has become a global leading platform with five commercialized blockbuster nano-formulation drugs, including Duomeisu (doxorubicin hydrochloride liposome), Keaili (albumin-bound paclitaxel), Duoenda (mitoxantrone hydrochloride liposome), Anfulike (amphotericin B cholesteryl sulfate complex) and irinotecan liposome.

Additionally, over 30 new formulation drugs are under development, with more than five key products with global patents. Amphotericin B liposome has applied marketing approval, 11 candidates are at clinical stage and over 20 new preparation candidates are at pre-clinical stage. Among the clinical stage assets, paclitaxel nanoparticles (fast dissolving), daunorubicin cytarabine liposome, and albumin-bound docetaxel are currently at pivotal/Ph3 studies.

Figure 15: CSPC's pipeline of new preparations



Source: Company data, CMBIGM. Notes: as of Aug 2023.

Figure 16: CSPC's advanced nano-formulation platform

Nano formulation development and manufacturing platform	Novel drug carrier design	✓	Invented Albumin nanoemulsion
		✓	Developed new cationic materials and new delivery system
	Novel drug delivery technology	✓	Invented ammonium salt gradient method of sulfobutylether β cyclodextrin and 5 sulfosalicylate
		✓	Cholesterol PEGylation modification method and post single layer PEGylation
	Novel preparation method	✓	Invented single phase solution lyophilization technology, O/W type Emulsification technology, crossflow mixing technology, continuous flow reaction technology etc.
		✓	Invented bottom up nanocrystal preparation technology, enabling continuous production
	Novel Industrialized production technology	✓	Invented continuous flow technology, employing linear amplifier overcome barriers to industrialized production
		✓	Illustrated that all nano drugs are able to be prepared by permutation and combination of four key processes
Nano formulation assessment system	Particle characterization method	✓	Developed nano formulation assessment technology for lipsome, albumin nanoparticles, emulsion, micelles, etc
	PK determination method	✓	Established multiple PK determination methods for nano drugs including lipsome, albumin nano particle, micelles, etc.
	Mature animal screening models	✓	Established multiple animal disease model for efficacy assessment
		✓	Established animal models for evaluating ABC phenomenon, CARPA response and HFS, enabling quick screening
	Particle characterization technique guided in vivo PK, PD, TOX evaluation	✓	Illustrated influence of drug release rate of lipsome, mode of administration and animal model on ABC phenomenon
		✓	Detailed study of CARPA and HFS laid the foundations for design of nanoparticles

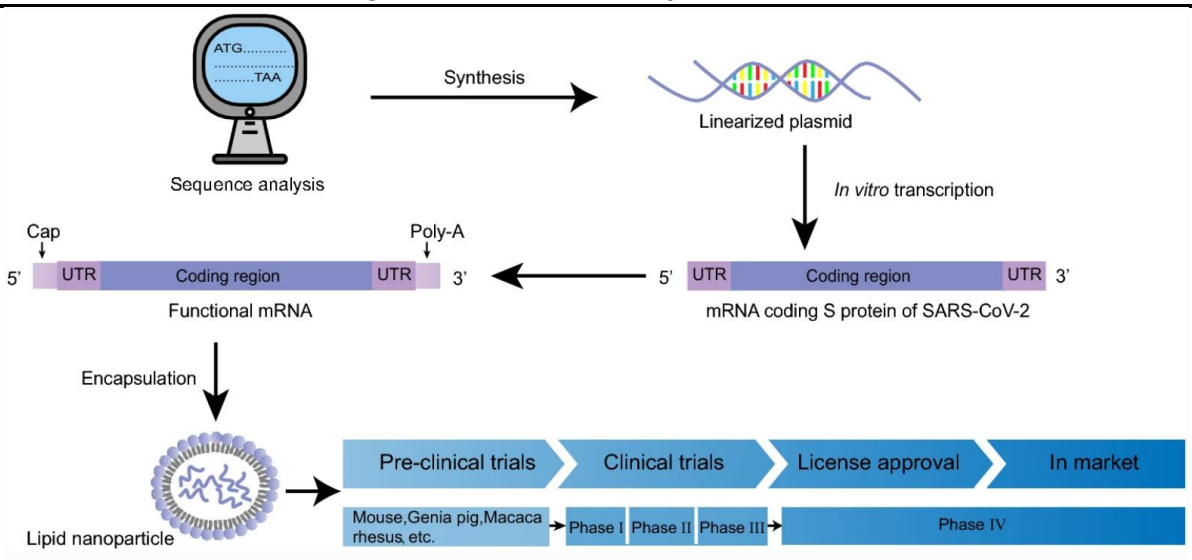
Source: Company data, CMBIGM

mRNA vaccine platform, nurtured the first domestic COVID mRNA vaccine approved in China

In Mar 2023, CSPC's lipid nanoparticles (LNP) delivering mRNA vaccine (SYS6006) was approved for emergency use in China for COVID-19, becoming the first domestic mRNA vaccine in China that has been granted for emergency use. The vaccine was initially put into use in May 2023.

The mRNA vaccines combines mRNA molecules with lipids to form LNPs. The 5'-capped mRNA is generated by in vitro reverse transcription (IVT) reaction using a linearized plasmid as a template. The mRNA molecules were designed according to the S protein sequence of the prototype SARS-CoV-2 strain and the key mutations of main epidemic variants. Purified mRNAs are encapsulated with lipids (mainly ionizable lipids, neutral phospholipids, PEGylated lipids, and cholesterol) to generate the mRNA-loaded LNP vaccines. After injection, the vaccines enter the host cells by endocytosis, then the mRNAs are released from LNPs and express S antigens by the ribosome, inducing immune responses.

Figure 17: Workflow of LNP-delivering mRNA vaccine development



Source: CMBIGM

CSPC is able to complete the mRNA synthesis internally, at a much lower cost. Adding 5'-cap to the mRNA sequence is one of the most expensive steps during the mRNA synthesis step. Instead of adding 5'-cap using enzymatic capping

in a two-step reaction, CSPC applies a one-step co-transcriptional reaction to add 5'-cap for the mRNA, and the capping reagent in the one-step reaction is produced internally and cost-effectively.

CSPC is also able to encapsulate mRNA-loaded LNPs internally without patent conflicts. The LNP-mRNA platform is a multi-component system that mainly consists of mRNA, ionizable lipids (可电离阳离子脂质), neutral phospholipids, PEGylated lipids, and cholesterol. The Company is able to produce mRNA-loaded LNP internally using its internal production equipment with in-house IPs, which could largely reduce production costs. CSPC has developed new type of lipid nanoparticles (LNPs), which could be easily captured by immune cells instead of normal tissues or the blood system. The Company also developed innovative technology to differentiate empty LNPs from mRNA-loaded LNPs, and reduce the rate of empty LNPs, leading to improved delivery efficiency and better safety profile. The Company's rich experiences in lipid research accumulated over past 20 years contribute to CSPC's successful development of mRNA vaccines.

The SYS6006 mRNA vaccine demonstrated promising efficacy. In a heterologous booster clinical study (SYS6006-008) of 4,000 participants conducted during the COVID-19 pandemic (from 10 Dec 2022 to 18 Jan 2023), using a recombinant protein vaccine as control, the efficacy of SYS6006 observed was 70.2% 7 to 28 days after booster vaccination and the efficacy of SYS6006 observed was 85.3% 14 to 28 days after booster vaccination (link1, link2). The product is stable and can be stored at 2-8°C for a long time.

SYS6006 adopts advanced technology with independent intellectual property rights, with the advantages of achieving higher production capacity, better process reproducibility, large-scale production and scale-up more easily.

CSPC is also promoting the development of new generations of SARS-CoV-2 mRNA vaccines against mutated strains targeting XBB1.5 and BQ.1.1, and the NDA is currently under review. In addition, the Company is actively developing other products on the platform, including rabies vaccine, RSV vaccine and VZV vaccine. Additionally, CSPC is exploring the application of LNP-delivering technology to CAR T-cell therapies.

CSPC has built a GMP-compliant mRNA production plant, with the manufacturing capacity of up to 1.5bn doses per year. CSPC is able to internally produce key raw materials and excipients which could significantly lower production costs.

CSPC maintained a leading position in China in mRNA vaccine development with SYS6006 already EUA approved. In China, several other companies have clinical-stage mRNA vaccine pipelines, including Abogenbio, RNACure, RiboBio, etc. Most of the current mRNA vaccine development focus on COVID-19, while LK101 from Likang Life is a Ph1 candidate exploring the application of solid tumors including lung cancer and liver cancer. Additionally, several mRNA vaccine candidates at IND stage in China target diversified indications such as rabies (AIM Vaccine), herpes zoster (Immorna) and gastric cancer (NeoCura).

Figure 18: Clinical-stage mRNA-based vaccine candidates in China

Drug name	Company	Chinese highest phase	Global highest phase	Target	Indication
SYS6006	CSPC	Approved (EUA)	Filed	SARS-CoV-2 S protein	COVID-19
ARCoVaX	Abogenbio, Walvax, Academy of Military Medical Sciences	Phase III	Phase III	SARS-CoV-2 S protein	COVID-19
RQ3013	RNACure, Fudan University, Walvax	Phase III	Phase III	SARS-CoV-2 S protein	COVID-19
RBMRNA-176	RiboBio, Argorna	Phase II	Phase II	SARS-CoV-2 S protein	COVID-19
LVRNA009	AIM Vaccine	Phase II	Phase III	SARS-CoV-2 S protein	COVID-19
tozinameran	BioNTech, Pfizer, Fosun	Phase II	Approved	SARS-CoV-2 S protein	COVID-19
SW0123	China Medical System, Stemirna Therapeutics	Phase I/II	Phase I/II	SARS-CoV-2 S protein	COVID-19
SW-BIC-213	Stemirna Therapeutics	Phase I	Phase III	SARS-CoV-2 S protein	COVID-19
LK101	Likang Life Sciences	Phase I	Phase I	N/A	Solid tumors
CS-2034	CanSino	IND	Phase II	SARS-CoV-2 S protein	COVID-19
LVRNA001	AIM Vaccine	IND	IND	RABV-G	Rabies
JCXH-105	Immorna	IND	Phase I	VZV	Herpes zoster
XH101	NeoCura	IND	IND	not available	Gastric cancer

Source: Pharmcube, CMBIGM

Figure 19: Global Ph3-stage mRNA-based vaccine candidates

Drug name	Company	Global highest phase	Target	Indication
elasomeran (Spikevax original)	Moderna	Approved	SARS-CoV-2 S protein	COVID-19
elasomeran+davesomeran (+Omicron BA.1)	Moderna	Approved	SARS-CoV-2 S protein	COVID-19
elasomeran+imelasomeran (+Omicron BA.4-5)	Moderna	Approved	SARS-CoV-2 S protein	COVID-19
mRNA-1345	Moderna	BLA filed	RSV fusion	RSV infection
mRNA-1273.815	Moderna	BLA filed	SARS-CoV-2 S protein	COVID-19
mRNA-1283.222	Moderna	Phase III	SARS-CoV-2	COVID-19
mRNA-1010	Moderna	Phase III	hemagglutinin	influenza
mRNA-1647	Moderna	Phase III	CMV	CMV infection
mRNA-1283	Moderna	Phase III	SARS-CoV-2 S protein	COVID-19
mRNA-4157	Merck & Co., Moderna	Phase III	N/A	melanoma
mRNA-1273.529	Moderna	Phase II/III	SARS-CoV-2 S protein	COVID-19
mRNA-1273.211	Moderna	Phase II/III	SARS-CoV-2 S protein	COVID-19
mRNA-1273.213	Moderna	Phase II/III	SARS-CoV-2 S protein	COVID-19
mRNA-1273.617.2	Moderna	Phase II/III	SARS-CoV-2 S protein	COVID-19
tozinameran+riltozinameran (+BA.1)	BioNTech, Pfizer	Approved	SARS-CoV-2 S protein	COVID-19
tozinameran+famtozinameran (+BA.4-5)	BioNTech, Pfizer	Approved	SARS-CoV-2 S protein	COVID-19
Comirnaty Omicron XBB.1.5	BioNTech, Pfizer	Approved	SARS-CoV-2 S protein	COVID-19
famtozinameran	BioNTech, Pfizer	BLA filed	SARS-CoV-2 S protein	COVID-19
PF-07252220	BioNTech, Pfizer	Phase III	hemagglutinin	influenza
BNT162b2s01	BioNTech, Pfizer	Phase III	SARS-CoV-2 S protein	COVID-19
riltozinameran	BioNTech, Pfizer	Phase III	SARS-CoV-2 S protein	COVID-19
BNT162b5	BioNTech, Pfizer	Phase II/III	SARS-CoV-2 S protein	COVID-19
abdavomeran	BioNTech, Pfizer, Fosun	Phase II/III	SARS-CoV-2 S protein	COVID-19
CVnCoV	CureVac, GSK	BLA filed	SARS-CoV-2 S protein	COVID-19
DS-5670	Daiichi Sankyo	BLA filed	SARS-CoV-2 S protein	COVID-19
ARCT-021	Arcturus Therapeutics	Phase III	SARS-CoV-2 S protein	COVID-19
PTX-COVID19-B	Providence, Everest Medicines	Phase III	SARS-CoV-2 S protein	COVID-19
ARCT-154	Arcturus Therapeutics	Phase III	SARS-CoV-2 S protein	COVID-19
LVRNA021	AIM Vaccine	Phase III	SARS-CoV-2	COVID-19
SWIM816	Stemirna Therapeutics	Phase II/III	SARS-CoV-2	COVID-19
HDT-301	Senai,Gennova, HDT Bio, Quratis	Phase II/III	SARS-CoV-2 S protein	COVID-19
ABO1020	Abogenbio	Phase II/III	SARS-CoV-2 S protein	COVID-19

Source: Pharmcube, CMBIGM

In the global market, Moderna and BioNTech/Pfizer are leading the mRNA space. Elasomeran from Moderna has been approved globally for COVID-19 original and Omicron BA.1/BA.4-5. Moderna has also submitted the marketing authorization application for the RSV mRNA vaccine mRNA-1345 in Jul 2023 (link). Additionally, Moderna has three Ph3 mRNA vaccine candidates for influenza, CMV infection and melanoma, and a Ph2 mRNA vaccine candidate for solid tumors. BioNTech/Pfizer have also developed the widely used COVID-19 vaccines Comirnaty, and the companies are conducting Ph3 studies for an influenza mRNA vaccine candidate. BioNTech is also developing a couple of mRNA vaccines for solid tumors.

Furthermore, based on CSPC's expertise in nucleic acid drug research, CSPC is also developing its siRNA platform for major chronic genetic diseases (such as gout, NASH and hypercholesterolemia) to fill the unmet clinical needs in the non-oncology field. Instead of using LNP delivery, the Company's siRNA platform applies the GalNAc technology with inhouse IP. We expect the Company to receive IND approval for its PCSK9 siRNA candidate by late-2023.

ADC platform, acheiving global out-licensing deals

CSPC has developed an innovative ADC platform internally with multiple programs under clinical development, including DP303c (HER2 ADC, Ph3), SYSA1801 (CLDN18.2 ADC, Ph1), SYS6002 (Nectin-4 ADC, Ph1), SYS6010 (EGFR ADC, Ph1), etc.

CSPC has developed a unique conjugation technology, which enables site-specific modification of certain glutamine (Gln, Q) amino acids in proteins by an engineered microbial transglutaminase (mTgase). ADC drugs have been covalently linked to Gln of mAb through mTGase to generate ADC drugs. Unlike existing ADC technologies, CSPC used native mAb without the need for protein engineering, resulting in minimal impact on properties of the antibodies. The procedure yields high coupling efficiency, and the ADC product is highly purified, active, and homogeneous.

Figure 20: Advantages of CSPC's ADC platform

ADC Design	Characteristics	Advantages
Conjugation mode	Engineering TGase catalysis	The specific conjugation on the homogeneous glutamine residue in the Fc region catalyzed by engineering modified TGase can produce highly purified ADC molecule with stable DAR ratio, favorable PK character and wide therapeutic index
Conjugation spot	Conserved Q295 residue on the heavy chain of the antibody	
Form of antibody	Intact homogeneous IgG	Avoid introducing mutation or deglycosylation that may lead to the increase of immunogenicity

Source: Company data, CMBIGM

DP303c (HER2 ADC) is the most advanced drug candidate on the Company's ADC platform, which is currently under Ph3 stage development. DP303c is a novel site-specific HER2-targeting ADC made up of a humanized IgG1 anti-HER2 antibody (DP001), an enzyme-based cleavable peptide-linker (LND1002), and two tubulin polymerization inhibitors (MMAE), using the Company's original conjugation and linker-payload technique. DP001 has the same amino acid sequence with trastuzumab (Herceptin). DP303c showed a high affinity with HER2 and could be effectively internalized. With average drug-to-antibody ratio (DAR) of 2.0, DP303c is a steady and homogenous DAR 2 ADC that was predicted to deliver a significant amount of the highly active MMAE inhibitor to tumor cells regularly. The drug candidate is designed to target HER2-positive cancers. In vitro and in vivo, DP303c showed stronger antitumor activities as compared to T-DM1 in a series of HER2-positive cancer cells and cell-derived xenograft (CDX) models, especially in the lower HER2-expressing cells. DP303c also exhibited high serum stability and a good PK profile.

DP303c is currently being evaluated in a Ph3 pivotal trial vs trastuzumab + chemo for HER2+ breast cancer (NCT05901935), a Ph2 pivotal trial for HER2+ breast cancer (NCT05334810), a Ph2 trial for HER2+ gastric cancer (NCT04826107), and a Ph2 trial for ovarian cancer (NCT04828616). The Company expects to file NDA by end-2023 for DP303c based on the results of the Ph2 study in HER2+ breast cancer.

CSPC has completed two out-licensing deals based on its ADC platform, marking the global recognition of the Company's ADC innovation capabilities. (1) SYSA1801 (Claudin18.2 ADC): In Jul 2022, CSPC entered into an exclusive license agreement with Elevation Oncology to out-license the ex-China rights of SYSA1801. CSPC has received an upfront payment of US$27mn and is also eligible to receive up to US$148mn in potential development and regulatory milestone payments and up to US$1.02bn in potential sales milestone payments, as well as tiered sales royalties. SYSA1801 is currently at Ph1 stage of development. (2) SYS6002 (Nectin-4 ADC): In Feb 2023, CSPC entered into an exclusive license agreement with Corbus Pharmaceuticals to out-license the rights of SYS6002 in the US, EU, UK, Canada, Australia, Iceland, Liechtenstein, Norway and Switzerland. CSPC will receive upfront payments of US$7.5mn and is also eligible to receive up to US$130mn in potential development and regulatory milestone payments and up to US$555mn in potential sales milestone payments, as well as tiered sales royalties. SYS6002 is currently at Ph1 stage of development.

Broad collaborations to expand pipelines and explore overseas opportunities

CSPC has forged broad collaborations with global and domestic partners by licensing-in, licensing-out, M&As, and strategic partnerships. The license-in deals and M&As help to expand the Company's product pipelines. CSPC has also achieved several license-out deals to explore the overseas potential of its pipelines.

Figure 21: Summary of collaborations of CSPC

Type of collaboration	Time	Partner	Products	Upfront payment	Milestone & royalties	Regions	Sources
License in	2022.12.17	Haihe Biopharma	Glumetinib (c-Met)	unknown	unknown	Greater China	Link
License in	2022.10.10	Harbour	Batoclimab/HBM9161 (FcRn)	RMB150mn	RMB50+400+411mn	Greater China	Link
License in	2021.11.22	Keymed	CM326 (TSLP, for treatment of asthma, COPD, etc)	RMB100mn	RMB100mn+royalties	China (exl. HK/Macau/TW)	Link
License in	2021.8.23	AlphaMab	KN026 (HER2-targeted bsAb)	RMB150mn	RMB450+450mn	China (exl. HK/Macau/TW)	Link
License in	2021.3.10	Keymed	CM310 (IL-4Rα, for treatment of asthma, COPD, etc)	RMB70mn	RMB100mn+royalties	China (exl. HK/Macau/TW)	Link
License in	2019.8.19	Synermore	Omalizumab biosimilar (IgE)	RMB10mn	RMB50mn+royalties	China (exl. HK/Macau/TW)	Link
License in	2019.2.26	SIMM	4 small molecule compounds	RMB34.3mn	RMB411.7mn+royalties	China	Link
License in	2019.1.4	Innogate	5 small molecule compounds	RMB25mn	RMB200mn+royalties	Greater China	Link
License in	2018.12.17	I-Mab Biopharma	TG103 (recombinant GLP-1 Fc fusion protein)	RMB15mn	RMB135mn+royalties	China (exl. HK/Macau/TW)	Link
License in	2018.9.25	Verastem	Copiktra/duvelisib (PI3K)	US$15mn	US$30mn+royalties	Greater China	Link
License out	2023.2.23	Corbus Pharma	SYS6002 (Nectin-4 ADC)	US$7.5mn	US$130+555mn	US, EU, UK, Canada, etc	Link
License out	2022.7.28	Elevation Ocology	SYSA1801 (Claudin18.2 ADC)	US$27mn	US$148+1020mn	Outside of Greater China	Link
License out	2021.8.17	Flame Biosciences	NBL-015 (Claudin 18.2 mAB)	US$7.5mn	US$172.5+460mn	Outside of Greater China	Link
M&A (54.8% stake acquired)	2022.2.8	Recomgen Biotech	Mingfule (rhTNK-tPA)	RMB154mn			Link
M&A (100% stake acquired)	2019.1.7	JMT	JMT101/JMT103	RMB252.88mn			Link
M&A (39.56% stake acquired)	2018.1.9	YZY Biopharma	M701/Y101D	RMB356mn			Link
Strategic alliance	2023.6.29	Pfizer	Nirmatrelvir/Ritonavir (3CL)	unknown			Link
Strategic alliance	2021.9.23	Keymed	one or more products in CNS	unknown			Link
Jointed venture (70%)	2019.5.7	Haihe Pharma	RMX1001,RMX1002, RMX2001, HH185 and CDK4/6)	RMB7mn			Link

Source: Company data, CMBIGM

In Aug 2023, CSPC's non-wholly owned subsidiary CSPC Innovation (300765 CH, CSPC held 74.2% stake) announced to acquire 51% stake in Megalith biopharmaceuticals, a wholly-owned subsidiary of CSPC, with a cash consideration of RMB1.87bn. If the deal is completed, CSPC's shareholding in Megalith will decrease from 100.0% to 86.8%. Megalith will continue to be a subsidiary of CSPC. We think the restructuring will help CSPC to accelerate its innovative pipeline development by leveraging the A-share market.

Megalith focuses on the cutting-edge fields of antibody drugs, ADCs, and mRNA vaccines, with multiple pipeline products that have great market potential. Megalith has more than 20 projects under development, including an mRNA COVID-19 vaccine SYS6006 that has been approved for emergency use in China, and 8 products in clinical trial or NDA stage, including 2 under NDA review, 3 in Ph2/3 trials and 3 in Ph1 trials.

Figure 22: Major pipeline products of Megalith biopharmaceuticals

Drug candidate	Target	Drug type	Indication	Stage
SYSA1802	PD-1	mAb	Cervical cancer	NDA filed
SYSA1903/omalizumab biosimilar	IgE	mAb	Chronic idiopathic urticaria	NDA filed
SYSA1501/DP303c	HER2	ADC	Breast cancer	Ph2/3
SYSA1901/pertuzumab biosimilar	HER2	mAb	Breast cancer	Ph3
SYSA1902/ustekinumab	IL-12/IL-23	mAb	Psoriasis	Ph3
SYSA1801	CLDN18.2	ADC	CLDN18.2 positive solid tumor	Ph1
SYS6002	Nectin-4	ADC	Solid tumor	Ph1
SYS6010	EGFR	ADC	Solid tumor	Ph1

Source: Company data, CMBIGM

Financial Analysis

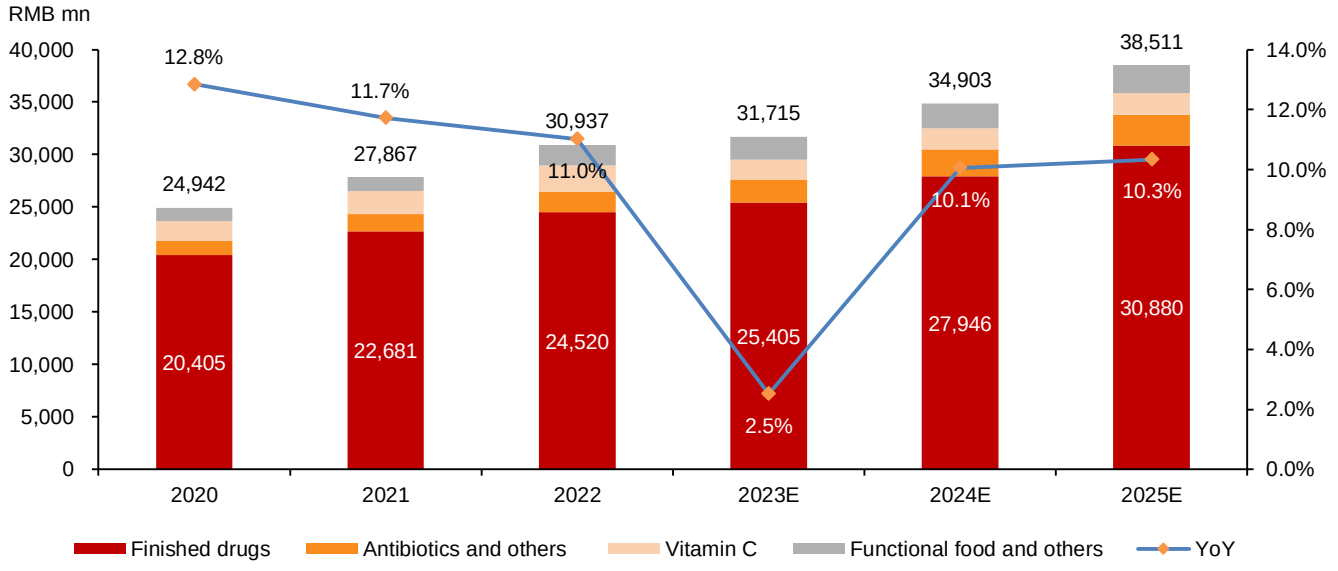
With the fast ramp-up of new products and stable sales of legacy products, we expect CSPC's revenue to grow 2.5% / 10.1% /10.3 YoY in FY23E/ 24E /25E to RMB31.7bn/ RMB34.9bn/ RMB38.5bn, respectively. The relatively low YoY sales growth rate of 2.5% in 2023 are mostly impacted by the reduced selling prices of Ke'Aili and Vitamin C. However, as the prices of Ke'Aili and Vitamin C to remain relatively stable, in our view, plus the strong growth of the Company's new products, we expect the Company's product sales to regain double digit growth rate in 2024 and 2025.

Figure 23: Sales projections by products

RMB mn	2022 (single drug sales from CMBI estimates)	2023E	2024E	2025E
Finished drugs	**24,520**	**25,405**	**26,676**	**28,009**
NBP	*6,989*	*7,659*	*8,042*	*8,283*
Oulaining	*315*	*267*	*227*	*205*
Xuanning	*1,638*	*1,556*	*1,556*	*1,556*
Duomeisu	*2,423*	*2,410*	*2,290*	*2,175*
Jinyouli	*2,335*	*2,487*	*2,611*	*2,690*
Ke'AiLi	*2,064*	*776*	*800*	*824*
New products	*750*	*1,350*	*1,890*	*2,741*
Other finished drugs	*8,006*	*8,899*	*10,530*	*12,407*
Antibiotics and others	**1,922**	**2,219**	**2,552**	**2,884**
Vitamin C	**2,529**	**1,888**	**1,982**	**2,081**
Functional food and others	**1,966**	**2,203**	**2,423**	**2,665**
Total revenue	**30,937**	**31,715**	**34,903**	**38,511**
YoY	*11.0%*	*2.5%*	*10.1%*	*10.3%*

Source: Company data, CMBIGM estimates

Figure 24: Segment sales forecasts



Source: Company data, CMBIGM estimates

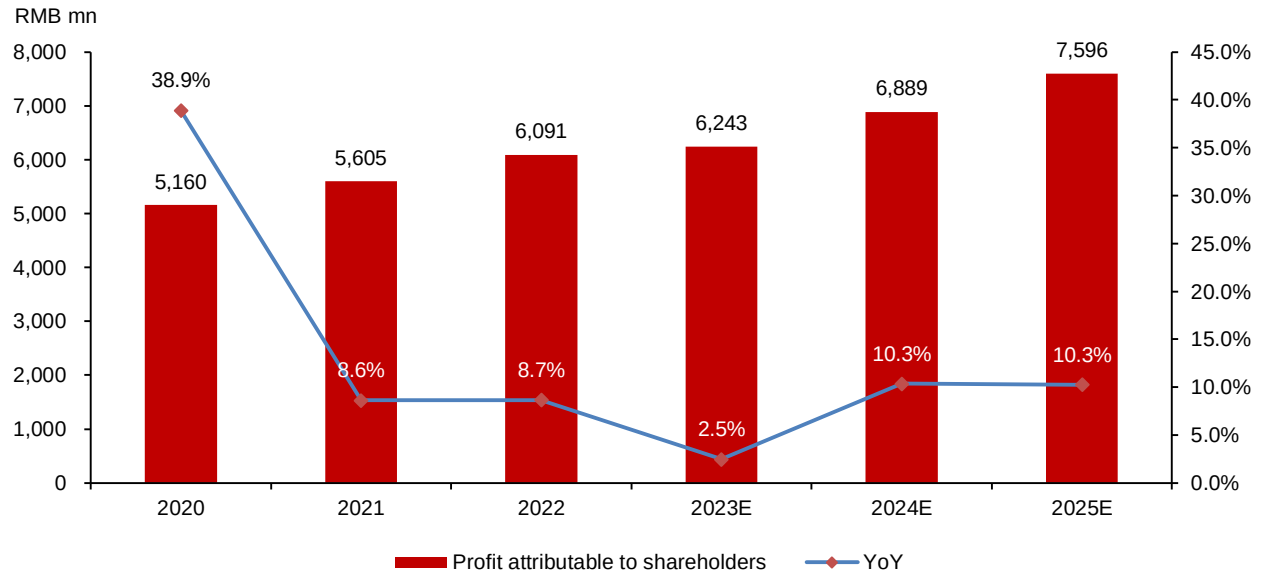
In FY23E/ 24E/ 25E, we expect CSPC's attributable net profit to grow 2.5%/ 10.3%/ 10.3 YoY to RMB6.2bn/ RMB6.9bn/ RMB7.6bn, respectively.

Figure 25: P&L forecasts

	2020	2021	2022	2023E	2024E	2025E
Revenue	**24,942**	**27,867**	**30,937**	**31,715**	**34,903**	**38,511**
Cost of sales & other operating costs	-6,257	-6,732	-8,680	-9,377	-10,471	-11,746
Gross profit	**18,685**	**21,135**	**22,256**	**22,338**	**24,432**	**26,765**
GPM	*75%*	*76%*	*72%*	*70%*	*70%*	*70%*
Other income and gains	642	654	895	530	584	644
% of revenue	*3%*	*2%*	*3%*	*2%*	*2%*	*2%*
Selling & distribution expenses	-9,378	-10,443	-10,337	-9,280	-10,331	-11,322
% of revenue	*-38%*	*-37%*	*-33%*	*-29%*	*-30%*	*-29%*
Administrative expenses	-946	-1,010	-1,173	-1,052	-1,187	-1,271
% of revenue	*-4%*	*-4%*	*-4%*	*-3%*	*-3%*	*-3%*
R&D expenses	-2,890	-3,433	-3,987	-4,617	-4,886	-5,314
% of revenue	*-12%*	*-12%*	*-13%*	*-15%*	*-14%*	*-14%*
Operating profit	**6,057**	**6,795**	**7,574**	**7,813**	**8,494**	**9,372**
% of revenue	*24%*	*24%*	*24%*	*25%*	*24%*	*24%*
Profit before tax	**6,391**	**6,847**	**7,582**	**7,760**	**8,563**	**9,443**
% of revenue	*26%*	*25%*	*25%*	*24%*	*25%*	*25%*
Income tax expense	-1,162	-1,159	-1,350	-1,350	-1,489	-1,642
Profit for the year	**5,229**	**5,688**	**6,232**	**6,411**	**7,074**	**7,801**
Minority interests	69	83	141	168	186	205
Profit attributable to shareholders	**5,160**	**5,605**	**6,091**	**6,243**	**6,889**	**7,596**
NPM	*21%*	*20%*	*20%*	*20%*	*20%*	*20%*
YoY	*38.9%*	*8.6%*	*8.7%*	*2.5%*	*10.3%*	*10.3%*

Source: Company data, CMBIGM estimates

Figure 26: Attributable net profit forecasts



Source: Company data, CMBIGM estimates

Valuation

We derived our 10-year DCF-based price target of HK$8.16 based on the assumptions of 11.85% WACC and 2.0% terminal growth rate.

Figure 27: DCF valuation

DCF Valuation (in RMB mn)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
EBIT	7,813	8,494	9,372	9,466	9,513	9,513	9,513	9,513	9,513	9,513
Tax rate	17.39%	17.39%	17.39%	17.39%	17.39%	17.39%	17.39%	17.39%	17.39%	17.39%
EBIT*(1-tax rate)	6,454	7,017	7,742	7,819	7,859	7,859	7,859	7,859	7,859	7,859
+ D&A	1,048	1,048	1,048	1,058	1,058	1,058	1,058	1,058	1,058	1,058
- Change in working capital	218	-130	-125	-126	-126	-126	-126	-126	-126	-126
- Capex	-800	-800	-800	-800	-800	-800	-800	-800	-800	-800
FCFF	**6,920**	**7,135**	**7,865**	**7,951**	**7,991**	**7,991**	**7,991**	**7,991**	**7,991**	**7,991**
Terminal value										**82,787**

Terminal growth rate	**2.00%**
WACC	**11.85%**
Cost of Equity	15.10%
Cost of Debt	5.00%
Equity Beta	1.10
Risk Free Rate	3.00%
Market Risk Premium	11.00%
Target Debt to Asset ratio	30.00%
Effective Corporate Tax Rate	15.00%
Terminal value (RMB mn)	27,027
Total PV (RMB mn)	70,707
Net debt (RMB mn)	-18,303
Minority interests (RMB mn)	1,592
Equity value (RMB mn)	87,418
# of shares (mn)	11,903
DCF per share (in HK$)	**8.16**

Source: CMBIGM estimates

Figure 28: CMBIGM earnings revisions

RMB mn	New			Old			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	31,715	34,903	38,511	32,555	34,884	37,482	-2.6%	0.1%	2.7%
Gross profit	22,338	24,432	26,765	22,462	24,768	26,237	-0.6%	-1.4%	2.0%
Operating profit	7,813	8,494	9,372	7,731	8,233	8,696	1.1%	3.2%	7.8%
Net profit	6,243	6,889	7,596	6,251	6,662	7,049	-0.1%	3.4%	7.8%
EPS (RMB)	0.52	0.58	0.64	0.53	0.56	0.59	-0.1%	3.4%	7.8%
Gross margin	70.43%	70.00%	69.50%	69.00%	71.00%	70.00%	+1.44ppt	-1ppt	-0.5ppt
Operating margin	24.63%	24.34%	24.34%	23.75%	23.60%	23.20%	+0.89ppt	+0.74ppt	+1.14ppt
Net margin	19.68%	19.74%	19.72%	19.20%	19.10%	18.81%	+0.48ppt	+0.64ppt	+0.92ppt

Source: Company data, CMBIGM estimates

Figure 29: CMBIGM earnings vs consensus

RMB mn	CMBI			Consensus			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	31,715	34,903	38,511	32,295	34,999	37,618	-1.8%	-0.3%	2.4%
Gross profit	22,338	24,432	26,765	22,814	24,908	26,924	-2.1%	-1.9%	-0.6%
Operating profit	7,813	8,494	9,372	7,578	8,299	8,752	3.1%	2.3%	7.1%
Attributable net profit	6,243	6,889	7,596	6,759	7,203	7,698	-7.6%	-4.4%	-1.3%
EPS (RMB)	0.52	0.58	0.64	0.52	0.57	0.60	0.9%	2.2%	6.2%
Gross margin	70.43%	70.00%	69.50%	70.64%	71.17%	71.57%	-0.21ppt	-1.17ppt	-2.07ppt
Operating margin	24.63%	24.34%	24.34%	23.46%	23.71%	23.27%	+1.17ppt	+0.62ppt	+1.07ppt
Net margin	19.68%	19.74%	19.72%	20.93%	20.58%	20.46%	-1.25ppt	-0.84ppt	-0.74ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Revenue	**24,942**	**27,867**	**30,937**	**31,715**	**34,903**	**38,511**
Cost of goods sold	(6,257)	(6,732)	(8,680)	(9,377)	(10,471)	(11,746)
Gross profit	**18,685**	**21,135**	**22,256**	**22,338**	**24,432**	**26,765**
Selling expense	(9,378)	(10,443)	(10,337)	(9,280)	(10,331)	(11,322)
Admin expense	(946)	(1,010)	(1,173)	(1,052)	(1,187)	(1,271)
R&D expense	(2,890)	(3,433)	(3,987)	(4,617)	(4,886)	(5,314)
Others	585	546	815	424	466	514
Operating profit	**6,057**	**6,795**	**7,574**	**7,813**	**8,494**	**9,372**
Gain/loss on financial assets at FVTPL	0	0	0	0	0	0
Share of (losses)/profits of associates/JV	347	60	33	(37)	60	60
Net Interest income/(expense)	**(12)**	**(8)**	**(25)**	**(15)**	**9**	**11**
Pre-tax profit	**6,391**	**6,847**	**7,582**	**7,760**	**8,563**	**9,443**
Income tax	(1,162)	(1,159)	(1,350)	(1,350)	(1,489)	(1,642)
Minority interest	69	83	141	168	186	205
Net profit	**5,229**	**5,688**	**6,232**	**6,411**	**7,074**	**7,801**
Gross dividends	1,528	1,691	2,097	1,873	2,067	2,279
Net dividends	39	9	9	2	10	10

BALANCE SHEET	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Current assets	**15,921**	**20,337**	**23,957**	**28,837**	**34,534**	**40,904**
Cash & equivalents	7,259	9,284	10,298	14,786	19,396	24,524
Account receivables	2,883	3,890	4,631	4,748	5,225	5,765
Inventories	1,861	2,480	2,555	2,760	3,082	3,457
Prepayment	0	0	0	0	0	0
ST bank deposits	1,535	1,443	3,575	3,575	3,575	3,575
Other current assets	2,382	3,240	2,898	2,969	3,257	3,583
Non-current assets	**14,149**	**14,405**	**17,813**	**17,565**	**17,317**	**17,069**
PP&E	7,770	8,529	9,582	9,579	9,577	9,574
Deferred income tax	117	43	113	113	113	113
Intangibles	509	468	1,908	1,818	1,727	1,637
Goodwill	1,164	1,035	1,395	1,240	1,085	930
Financial assets at FVTPL	1,877	1,979	2,126	2,126	2,126	2,126
Other non-current assets	2,711	2,351	2,689	2,689	2,689	2,689
Total assets	**30,070**	**34,742**	**41,770**	**46,402**	**51,851**	**57,973**
Current liabilities	**6,302**	**7,226**	**8,958**	**9,072**	**9,534**	**10,155**
Short-term borrowings	99	0	153	(342)	(838)	(1,334)
Account payables	4,759	6,162	6,864	7,414	8,279	9,287
Tax payable	379	261	262	262	262	262
Other current liabilities	1,065	803	1,679	1,739	1,832	1,940
Non-current liabilities	**667**	**687**	**1,170**	**1,170**	**1,170**	**1,170**
Long-term borrowings	0	0	0	0	0	0
Other non-current liabilities	667	687	1,170	1,170	1,170	1,170
Total liabilities	**6,969**	**7,913**	**10,128**	**10,242**	**10,704**	**11,325**
Share capital	10,899	10,899	10,899	10,899	10,899	10,899
Other reserves	11,433	15,087	19,298	23,668	28,490	33,807
Total shareholders equity	**22,332**	**25,987**	**30,198**	**34,567**	**39,389**	**44,707**
Minority interest	769	842	1,444	1,592	1,757	1,941
Total equity and liabilities	**30,070**	**34,742**	**41,770**	**46,402**	**51,851**	**57,973**

CASH FLOW	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	**6,391**	**6,847**	**7,582**	**7,760**	**8,563**	**9,443**
Depreciation & amortization	809	865	1,048	1,048	1,048	1,048
Tax paid	(1,061)	(1,141)	(1,335)	(1,350)	(1,489)	(1,642)
Change in working capital	1,680	(1,388)	798	218	(130)	(125)
Others	(1,079)	(547)	(467)	0	0	0
Net cash from operations	**6,740**	**4,637**	**7,627**	**7,677**	**7,993**	**8,723**
Investing						
Capital expenditure	(1,356)	(1,410)	(2,220)	(800)	(800)	(800)
Acquisition of subsidiaries/ investments	0	0	0	0	0	0
Others	(773)	773	(4,576)	0	0	0
Net cash from investing	**(2,130)**	**(637)**	**(6,796)**	**(800)**	**(800)**	**(800)**
Financing						
Dividend paid	(1,528)	(1,691)	(2,097)	(1,873)	(2,067)	(2,279)
Net borrowings	169	0	486	0	0	0
Proceeds from share issues	0	0	0	0	0	0
Share repurchases	0	(264)	(14)	0	0	0
Others	(112)	(242)	(279)	(516)	(516)	(516)
Net cash from financing	**(1,471)**	**(2,197)**	**(1,904)**	**(2,389)**	**(2,583)**	**(2,795)**
Net change in cash						
Cash at the beginning of the year	4,118	7,259	9,060	10,298	14,786	19,396
Exchange difference	2	(2)	14	0	0	0
Others	0	0	0	0	0	0
Cash at the end of the year	**7,259**	**9,060**	**8,001**	**14,786**	**19,396**	**24,524**

GROWTH	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Revenue	12.8%	11.7%	11.0%	2.5%	10.1%	10.3%
Gross profit	17.4%	13.1%	5.3%	0.4%	9.4%	9.5%
Operating profit	31.7%	12.2%	11.5%	3.1%	8.7%	10.3%
Net profit	40.1%	8.8%	9.6%	2.9%	10.3%	10.3%

PROFITABILITY	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Gross profit margin	74.9%	75.8%	71.9%	70.4%	70.0%	69.5%
Operating margin	24.3%	24.4%	24.5%	24.6%	24.3%	24.3%
Return on equity (ROE)	25.6%	23.5%	22.2%	19.8%	19.1%	18.6%

GEARING/LIQUIDITY/ACTIVITIES	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Net debt to equity (x)	(0.4)	(0.4)	(0.4)	(0.5)	(0.6)	(0.6)
Current ratio (x)	2.5	2.8	2.7	3.2	3.6	4.0
Receivable turnover days	73.4	92.9	87.7	87.7	87.7	87.7
Inventory turnover days	108.6	134.5	107.4	107.4	107.4	107.4
Payable turnover days	294.5	352.4	319.6	319.6	319.6	319.6

VALUATION	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
P/E	18.4	16.8	14.2	9.9	9.0	8.2
P/E (diluted)	18.4	16.8	14.2	9.9	9.0	8.2
P/B	4.1	3.5	2.7	1.7	1.5	1.3
P/CFPS	14.1	20.3	11.4	8.1	7.8	7.1
Div yield (%)	1.6	1.8	2.4	3.0	3.3	3.7

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

Disclosures & Disclaimers

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