

Kintor Pharmaceutical Limited

開拓藥業有限公司

(9939.HK)

Business Overview

Kintor Pharmaceutical Limited (“The Company”) is a clinical-stage novel drug developer in China focused on the proprietary R&D of potential first-in-class and best-in-class drugs for cancers and other androgen receptor-related or AR-related diseases. The Company’s lead drug candidate, Proxalutamide, is a potential best-in-class drug undergoing phase III clinical trials in China and phase II clinical trials in the United States for metastatic castration-resistant prostate cancer, or mCRPC as well as clinical trials for breast cancer. Its mission is to become a global leader in the research, development and commercialization of innovative therapies, focusing on indications with substantial unmet medical needs, in particular in the AR-related field. The portfolio of drug candidates addresses major cancer types and other AR-related diseases with large market potential. According to the Frost & Sullivan Report, prostate cancer was the second fastest growing cancer among major cancer types in China in terms of the growth rate of new cases from 2014 to 2018, and breast cancer was the most common type of cancer in women globally in 2018. The population of male patients aged 30 to 70 with androgenetic alopecia, a common form of hair loss and an AR-related disease, reached over 92.8 million in China and 31.1 million in the United States in 2018, respectively, according to the Frost & Sullivan Report.

The Company had developed a pipeline of five drug candidates as of the Latest Practicable Date, for which it had obtained approvals to commence clinical trials in China, the United States and/or Taiwan. These clinical-stage drug candidates are composed of a phase III small molecule drug candidate, a phase II small molecule drug candidate, a phase II monoclonal antibody drug candidate, a phase I mTOR inhibitor drug candidate and an inhibitor of the hedgehog signal translation pathway for which it received IND approval in February 2020 as follows:

Basic Information

Offer Price

HK\$17.8-HK\$20.15

Offer Size

92,347,500 Shares, comprise of Public Offer 9,235,000 Shares and International Offer 83,112,500 Shares (subject to reallocation and Over-allotment Option)

Market Capitalization

\$6,575.1m-\$7,443.2m

Application Period

12 May 2020 – 15 May 2020, Noon

Listing Date

22 May 2020

Board Lot

500 shares

Major Shareholders

KG Development	26.64%
Real Able Limited	7.31%
Mr. Stephen Hui Wang	7.06%
Highlight Medical	5.22%
Sungent Venture Limited	5.04%
Origin VC	4.86%

Sole Sponsors

Huatai International

Joint Global Coordinators

Huatai International, UBS, CICC

Joint Lead Managers

CMB International, China Renaissance, Haitong International, CCB International, Everbright Sun Hung Kai



Proxalutamide (GT0918) (普克魯胺): Proxalutamide is the lead drug candidate and is in phase III clinical trials in China for mCRPC with a targeted submission of NDA in 2020. It is also undergoing phase II clinical trials for mCRPC in the United States. Proxalutamide is a potential best-in-class small molecule AR antagonist for the treatment of mCRPC based on well-researched AR mechanism and has a novel chemical structure that enables it to down regulate AR expression. As of 31 December 2019, it had been granted 20 patents relating to Proxalutamide's compound, synthetic methods and uses in the PRC, the United States, Japan, South Korea, South Africa, Germany, France, the United Kingdom, Denmark, Ireland, Italy, Luxembourg, the Netherlands, Poland, Sweden, Australia, Canada, Russia and Macau. All these patents are scheduled to expire in 2030 and 2032, respectively.

Pyrilutamide (KX-826) (福瑞他恩): Pyrilutamide is in phase II clinical trials in China for androgenetic alopecia with expected first patient enrolment in the second half of 2020. It is also in phase Ib clinical trials for androgenetic alopecia in the United States and it commenced first patient enrolment in January 2020 and The Company expects to complete these trials in 2020. As of 31 December 2019, it had been granted 12 patents relating to KX-826's synthetic methods and uses in the PRC, the United States, Japan, South Korea, South Africa, Switzerland, Germany, France, the United Kingdom, Canada and Macau which are scheduled to expire in 2030.

ALK-1 (GT90001): ALK-1 is in phase II clinical trials in Taiwan as a combination therapy with Nivolumab, a PD-1, for metastatic HCC (hepatocellular carcinoma) and is a potential first-in-class antibody for which it obtained an exclusive global license from Pfizer. The Company expects to conduct MRCT for ALK-1 globally, and has obtained the acceptance notice for ALK-1's MRCT for both monotherapy and combination therapies from the CDE.

Detorsertib (GT0486) (迪拓賽替): Detorsertib is in phase I clinical trials in China for metastatic solid tumours. Detorsertib is a second-generation mTOR inhibitor that inhibits both mTORC1 and mTORC2, and has shown greater therapeutic advantages as compared with first-generation mTOR inhibitors that only inhibit mTORC1. As of the Latest Practicable Date, there was no mTORC1/mTORC2 dual inhibitor that had been approved for marketing globally. The Company believes Detorsertib has the potential to become a first-in-class dual mTORC1/mTORC2 inhibitor addressing significant unmet medical needs. As of 31 December 2019, it had one pending patent application in the PRC and seven patent applications overseas relating to mTOR kinase inhibitor's compound. The patents from these currently pending patent applications, if granted, would be scheduled to expire in 2037.

Hedgehog/SMO Inhibitor (GT1708F): GT1708F is an inhibitor of the hedgehog signal transduction pathway. The Company is currently developing GT1708F primarily for the treatment of leukaemia and BCC. It obtained IND approval for GT1708F from the NMPA in February 2020 and The Company expects to commence patient enrolment in the third quarter of 2020. As of 31 December 2019, it had been granted four patents in the PRC and five patents in the United States, Germany, France, the United Kingdom and Australia relating to Hedgehog's compound, which were expected to expire between 2033, 2034 and 2037.



Drug Candidate	Target/ Mechanism	Indication ⁽¹⁾	Country/ Region	Pre-Clinical	IND Filing (Filed) / (Accepted)	Phase I	Phase II	Phase III	NDA
Clinical Stage Products	Proxalutamide (GT0918) (普克魯胺) (Core Product)	Second generation AR antagonist	mCRPC	China	Expected to submit NDA in 2020 ⁽²⁾				
			Combination therapy with Abiraterone for mCRPC	China	Expected to complete phase III in 2021				
			Combination therapy with a PARP inhibitor for mCRPC	China	Δ				
			mCRPC	US	Expected to complete phase II in 2020				
			Metastatic breast cancer*	China					
			Combination therapy with Exemestane, Letrozole and Fulvestrant for metastatic breast cancer*	China					
	Pyrilutamide (KX-826) (福瑞他恩) (Core Product)	AR antagonist (for external use)	Androgenetic alopecia*	China	Expected to complete phase II in 2020				
			Androgenetic alopecia*	US	Expected to complete phase Ib in 2020				
			Acne vulgaris*	China/US					
	ALK-1 (GT90001) ⁽³⁾	Angiogenesis inhibitor	Combination therapy with a PD-1 for metastatic HCC*	Taiwan					
Liver cancer* (monotherapy or combination therapy)			Global MRCT		Δ				
Detorsertib (GT0486) (迪拓賽替)	mTOR kinase inhibitor	Metastatic solid tumours*	China						
GT1708F ⁽⁴⁾	Hedgehog/ SMO inhibitor	Leukaemia and BCC	China			Δ			
		Leukaemia and BCC	US						
Pre-Clinical Products	AR degrader	Prostate cancer and AR-related diseases							
	c-Myc inhibitor ⁽⁵⁾	Blood cancer							
	IDO inhibitor	Multiple types of cancers							

Figure 1 Summary of drug candidates

Financial Highlights

Consolidated Statement of Comprehensive Income For the year ended 31 December		
	2018	2019
	RMB'000	
Revenue	698	0
COGS	(689)	0
Gross Profit	9	0
Other income	12,298	19,018
Distribution and marketing costs	0	(336)
Administrative expenses	(24,104)	(32,763)
R&D costs	(93,198)	(214,019)
Other gains/losses - net	518	(587)
Operating profit	(104,477)	(228,687)
Finance cost-net	(4,007)	(3,890)
Profit/loss for the year	(108,484)	(232,577)

Consolidated Statement of Financial Position
For the year ended 31 December

	2018	2019
	RMB'000	
Non-current assets	205,254	332,763
Current assets	218,343	220,613
Current liabilities	108,385	142,583
Net current assets	109,958	78,030
Non-current liabilities	63,535	41,129
Net assets	251,677	369,664

Consolidated Statement of Cash Flow
For the year ended 31 December

	2018	2019
	RMB'000	
Cash used in operation before changes in working capital	(107,578)	(226,071)
Changes in working capital	(3,723)	145
Net interest paid	(3,567)	(2,116)
Net cash used in operating activities	(114,868)	(228,042)
Net cash used in investing activities	(64,748)	(7,013)
Net cash generated from financing activities	303,936	295,852
Net increase in cash and cash equivalents	124,320	60,797
Cash and cash equivalent at the beginning	13,193	137,513
Exchange losses on cash and cash equivalents	0	(2,778)
Cash and cash equivalent at the end	137,513	195,532

Reallocation of Shares Offered

Times of HK Offer Shares Subscription	15X - 50X	50X - 100X	Over 100X
% of total shares reallocated to HK Offer	30%	40%	50%

Use of Proceed

The company estimates that it will receive net proceeds of approximately HK\$1,642.7 million after deducting the underwriting fees and expenses payable by them in the Global Offering, assuming no Over-allotment Option is exercised and assuming an Offer Price of HK\$18.98 per Offer Share,

- approximately 42% or HK\$689.9 million allocated to development and commercialization of Proxalutamide as follows:



- (i) approximately 27%, or HK\$443.5 million, will be used to clinical trials.
- (ii) approximately 9%, or HK\$147.8 million, will be used to manufacturing.
- (iii) approximately 6%, or HK\$98.6 million, will be used to sales and marketing.
- approximately 28%, or HK\$460 million allocated to development and commercialization of Ppyrilutamide as follows:
 - (i) approximately 13%, or HK\$213.6 million, will be used to clinical trials.
 - (ii) approximately 8%, or HK\$131.4 million, will be used to manufacturing.
 - (iii) approximately 7%, or HK\$115 million, will be used to sales and marketing.
- approximately 4%, or HK\$65.7 million, to be used to development for clinical stage drug candidate ALK-1.
 - (i) approximately 3%, or HK\$49.3 million, to clinical trials of ALK-1 in China.
 - (ii) approximately 1%, or HK\$16.4 million, to application for clinical trials registration and the manufacture of ALK-1.
- approximately 4%, or HK\$65.7 million, to be used to development for clinical stage drug candidate Detorsertib.
 - (i) approximately 0.5%, or HK\$8.2 million, to clinical trials of Detorsertib in China.
 - (ii) approximately 3.5%, or HK\$57.5 million, to manufacture of Detorsertib.
- approximately 4%, or HK\$65.7 million, to be used to development for clinical stage drug candidate GT1708F.
 - (i) approximately 0.5%, or HK\$8.2 million, to clinical trials of GT1708F in China.
 - (ii) approximately 3.5%, or HK\$57.5 million, to manufacture of GT1708F.
- approximately 2%, or HK\$32.9 million, to be used to other clinical study projects.
- approximately 6%, or HK\$98.6 million, to be used to R&D of pre-clinical stage drug candidates.
- approximately 10%, or HK\$164.3 million, to be used to working capital and general corporate purpose.

Cornerstone Placing

The Company has entered into the Cornerstone Investment Agreement with the following cornerstone investors, pursuant to which the Cornerstone Investors have agreed to subscribe for a certain number of offer shares at the offer price for an aggregate amount of US\$115,000,000.

Cornerstone Investor	Investment Amount	No. of share to be subscribed for	Approx. % of total number of offer shares	Approx. % following completion of the Global Offering
HK\$17.8 (low end of the indicative offer price range)				
Zhuhai Gree Financial Investment Management Co.Ltd	USD 98,000,000	42,699,000	46.24%	11.56%
Foresight Orient Global Superior Choice SPC	USD 5,000,000	2,178,500	2.36%	0.59%
Highlight Medical	USD 5,000,000	2,178,500	2.36%	0.59%
Cherry Cheeks	USD 7,000,000	3,049,500	3.30%	0.83%
Total	USD 115,000,000	50,105,500	54.26%	13.57%
*assuming over-allotment option is not exercised				
HK\$18.98 (mid point of the indicative offer price range)				
Zhuhai Gree Financial Investment Management Co.Ltd	USD 98,000,000	40,044,000	43.36%	10.84%
Foresight Orient Global Superior Choice SPC	USD 5,000,000	2,043,000	2.21%	0.55%
Highlight Medical	USD 5,000,000	2,043,000	2.21%	0.55%
Cherry Cheeks	USD 7,000,000	2,860,000	3.10%	0.77%
Total	USD 115,000,000	46,990,000	50.88%	12.71%
*assuming over-allotment option is not exercised				
HK\$20.15 (high end of the indicative offer price range)				
Zhuhai Gree Financial Investment Management Co.Ltd	USD 98,000,000	37,719,000	40.84%	10.21%
Foresight Orient Global Superior Choice SPC	USD 5,000,000	1,924,000	2.08%	0.52%
Highlight Medical	USD 5,000,000	1,924,000	2.08%	0.52%
Cherry Cheeks	USD 7,000,000	2,694,000	2.92%	0.73%
Total	USD 115,000,000	44,261,000	47.92%	11.98%
*assuming over-allotment option is not exercised				

Risks Factors

Risks Relating to Financial Prospects

- The Company is a pre-revenue biopharmaceutical company with a history of losses. Financial prospects in the foreseeable future depend on the successful commercialization of drug candidates. If The Company fails to commercialize any of drug candidates or otherwise to become or remain profitable, investors may lose all or substantially all of investment.
- The Company may need to obtain substantial additional funding for operations
- The Company had net operating cash outflow during the Track Record Period
- Raising additional capital may cause dilution to shareholders and restrict operations.



- Intangible assets constitute a substantial portion of total assets; if The Company determines intangible assets to be impaired, it would adversely affect results of operations.
- Investment products which are classified as financial assets measured at amortized costs are subject to credit risks, and fair value changes for financial assets measured at fair value through profit or loss are subject to valuation uncertainty due to the use of unobservable inputs, which may cause volatility and adversely affect financial condition and results of operations.
- The Company's drug candidates are subject to extensive regulation, and The Company cannot assure any of drug candidates will receive regulatory approvals.

Risks Relating to Commercialization of Drug Candidates

- There is no assurance that The Company will be able to successfully commercialize only phase-III clinical-stage drug candidate, Proxalutamide.
- Drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.
- The Company face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than The Company does.
- The patient pool for drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- The Company may not be able to effectively build and manage sales network and implement marketing strategies.
- Even if The Company is able to commercialize any drug candidates, the drugs may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which could harm the business.

Risks Relating to Global Offering

- No public market currently exists for shares; the market price of shares may be volatile and an active trading market for shares may not develop.
- The Company cannot make fundamental changes to business without the consent of the Stock Exchange
- Investors will incur immediate and significant dilution and may experience further dilution if The Company issues additional Shares in the future.
- The Company's Controlling Shareholders have significant influence over The Company and their interests may not be aligned with the interests of other Shareholders.
- Because The Company does not expect to pay dividends in the foreseeable future after the Global Offering, investors must rely on price appreciation of shares for a return on investment.

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