Tuesday, September 27, 2022

Company Report

China Merchants Securities (HK) Co., Ltd.
Hong Kong Equity Research

Sino Biopharm (1177 HK)

Co in-licensed pan-PPAR agonist lanifibranor for NASH

- **SBP in-licensed a ph3 NASH candidate, lanifibranor, from French-based Biotech Inventiva for exclusive China rights (up to USD302mn in biobucks)**
- **NASH presents high risk for serious liver damage with enormous market opportunity (~1.5-6.45% prevalence), while no approved drug so far**
- **We like Co's bonafide intention for focused R&D and steady steps towards innovative transformation. Maintain BUY with TP at HKD5.4**

Co in-licensed lanifibranor for exclusive China rights

On Sep 22th, Co announced its subsidiary CTTQ in-licensed a ph3 NASH asset, lanifibranor (pan-PPAR agonist) from Inventiva for exclusive China rights. Per the pact, CTTA will pay Inventiva 1) an upfront payment of USD12mn, and 2) up to USD290mn of clinical, regulatory and commercial milestone payments (o/w an expected USD5mn in the short term), along with 3) tiered royalty from high single-digit to mid-teen during first 3 yrs and low- and mid-teen afterwards.

The NASH assets further strengthen Co's hepatitis franchise

We think lanifibranor offers some scientific and clincial attractiveness in the competitive NASH landscape: **1) Orally available Pan-PPAR:** lanifibranor is the only oral pan-PPAR (PPARα, PPARδ, PPARγ) agonist under clinical development (*Fig 7*). **2) Positive NATIVE Ph2b data:** the study showed numerical better outcome over dual-PPAR agonists (*Fig 7,* NASH resolution and no worsening of fibrosis: lanifibranor v.s Elafibranor 49% v.s 24.5%, non-head-to-head trial). **3) Fast-mover asset**: Given scientific challenge within NASH space, we reckon the addition of lanifibranor should enrich Co.'s NASH pipeline and further strengthen its hepatitis franchise (*Fig 8*). The ph3 MRCT NATiV3 (Part 1) trial (n=900, w/o Chinese pts) targets composite primary endpoints of NASH resolution and no worsening of fibrosis). The study is expected to complete enrolment in 2H24E and provide topline results in 1H25. CTTQ will either join the ongoing NATiV3 ph3 clinical trial or run an independent study in China.

Unmet medical needs within NASH space

Nonalcoholic steatohepatitis (NASH) is a serious form of non-alcoholic fatty liver disease (NAFLD) that is characterized by liver inflammation, hepatocellular injury and different degrees of fibrosis[1]. **1) unmet medical needs:** NASH pts bears ~20% risk of progressing chronically to cirrhosis where liver function is permanently damaged and potentially further deteriorates into liver cancer; however, no effective drug has been approved so far[2]. Prevalence of NASH is approximately ~1.5-6.45% worldwide, and is estimated to be a leading cause of liver transplant[3,4]. **2) NASH R&D remains challenging:** According to clinicalTrials.gov, there are 15 assets under 18 on-going Ph3 trials globally (*Fig 6*). As challenged by complex multi-pathway engaging pathogenesis, several closely watched late-stage NASH drug candidates have experienced major setbacks (*Fig 9*), e.g GenFit's dual PPAR agonist Elafibranor (link).

RMB mn	2019	2020	2021	2022E	2023E
Revenue	24,234	23,647	26,861	29,340	33,246
Growth	16%	-2%	14%	9%	13%
Adj. underlying profit*	3,125	3,114	2,931	3,147	3,590
Growth	12%	0%	-6%	7%	14%
EPS (HKD)	0.17	0.14	0.12	0.19	0.22
P/E (x)	24.4	28.9	34.5	21.0	18.4
P/B (x)	5.1	4.6	2.6	2.4	2.3
Dividend yield (%)	2.0	2.0	2.0	2.1	1.9

Sources: Company data, CMS (HK) estimates; price as of Sep 27, 2022
*Notes: * derived from reported net profit after excluding non-recurring items*

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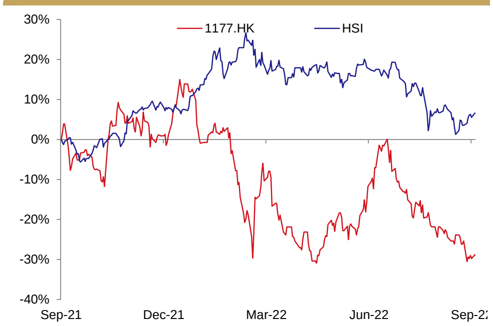
WHAT'S NEW
Event updates

BUY

Previous	BUY
Price (Sept 27, 2022)	HKD3.74
12-month Target Price (Potential up/downside)	HKD5.4 (+46%)
Previous	HKD5.4

Price Performance



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%	1m	6m	12m
1177 HK	(-8.9)	(22.6)	(38.2)
HSI	(0.1)	(9.5)	(6.3)

Pharmaceutical & Healthcare	
Hang Seng Index (Sep 27, 2022)	17,860
HSCEI (Sep 27, 2022)	6,150
Key Data	
52-week range (HKD)	3.6-6.5
Market cap (HKD mn)	70,368
Avg. daily volume (HKD mn)	173.6
BVPS (HKD)	1.7
Shareholding Structure	
Tse family	41.9%
Free float	58.1%

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Related Research

1. Sino Biopharm (1177 HK) – Soft 1H22 results (BUY) (Aug 24, 2021)
2. Sino Biopharm (1177 HK) – VBP headwind persistently weigh on legacy portfolio (BUY) (Apr 6, 2021)
3. Sino Biopharm (1177 HK) – Sinovac investment cushion GPO headwind (HOLD) (Sep 7, 2021)
4. Sino Biopharm (1177 HK) – New products to fuel growth recovery in 2021E (HOLD) (Mar 23, 2021)

NASH R&D remains challenging with mixed outcomes from late-stage trials

Figure 9: Ph2/3 clincial trial outcome for NASH drug candidates

Company	Drug name	MoA	Phase (Trial name)	Enrollment	Indication	Results outcome	Topline data	Publish Date	NCT Number
Madrigal	Resmetirom	THR β agonist	Ph 3 (MAESTRO-NAFLD-1)	169	NASH	Positive	MRI-PDFF: **-47.7% vs -6%**	2022-6-25	NCT04197479
Intercept	obeticholic acid	FXR agonist	Ph 3 (REGENERATE), CRL	931	NASH (F2-F3 fibrosis)	Positive	fibrosis improvement of ≥1 stage with no worsening of NASH: **23% vs 12% (p=0.0002),** NASH resolution with no worsening of fibrosis: **12% vs 8% (p=0.13)**	2019-12-05	NCT02548351
Inventiva	lanifibranor	Pan-PPAR (α/δ/ɣ)	Ph 2 (NATIVE)	247	NASH	Positive	fibrosis improvement of ≥1 stage with no worsening of NASH: **48% vs 29%** NASH resolution and no worsening of fibrosis: **49% v.s 22%, (P<0.001)**	2021-10-21	NCT03008070
Genefit	elafibranor	PPARα/δ	Ph 3 (RESOLVE-IT)	1070	NASH	Negative	NASH resolution without worsening of fibrosis: **19.2% vs 14.7%, (p=0.0659)**	2020-05-11	NCT02704403
Zydus	Saroglitazar	PPARα/ɣ	Ph 2	106	NASH	Positive	ALT level change (4mg 16 wks): **-45.8% v.s 3.4%**	2021-04-02	NCT03061721
Takeda	pioglitazone	PPARγ	Ph 2 (PIVENS)	247	NASH	Negative	Improvement in histologic features of NASH **34% vs 43% / 19% (Vitamin E / PbO)**	2010-05-06	NCT00063622
Novo Nordisk	Semaglutide	GLP-1	Ph2	320	NASH	Positive	NASH resolution without worsening of fibrosis: **58.9% vs 17.2%**	2020-05-06	NCT02970942
Akero	Efruxifermin	FGF21	Ph 2b (HARMONY)	128	NASH (F2-F3 fibrosis)	Positive	fibrosis improvement of ≥1 stage with no worsening of NASH: **41% vs 20%**	2022-09-13	NCT04767529
			Ph 2 (BALANCED)	30	NASH (cirrhosis)	Positive	fibrosis improvement of ≥1 stage with no worsening of NASH: **33% vs 0%**	2022-08-22	NCT03976401
Galmed	Aramchol	SCD1 inhibitor	Ph 3 (ARMOR)	46	NASH	Positive	fibrosis improvement of ≥1 based on CRN: **40%**	2022-04-28	NCT04104321

Figure 9: Ph2/3 clincial trial outcome for NASH drug candidates

Company	Drug name	MoA	Phase (Trial name)	Enrollment	Indication	Results outcome	Topline data	Publish Date	NCT Number
Sanofi	rimonabant	CB1 antagonist	Ph 3	165	NASH	**Terminated**	terminated (company decision taken in light of demands by certain national health authorities)	2016-05-18	NCT00576667
Gilead	selonsertib	ASK1 inhibitor	Ph 3 (STELLAR-4)	877	NASH (F4 cirrhosis)	**Negative**	fibrosis improvement of ≥1 stage with no worsening of NASH: **14.4% vs 12.8% (p=0.93)**	2020-03-05	NCT03053063
			Ph 3 (STELLAR-3)	802	NASH (F3 fibrosis)	**Negative**	fibrosis improvement of ≥1 stage with no worsening of NASH: **12.1% vs 13.2% (p=0.93)**	2020-03-05	NCT03053050
Summit Internal Medicine	cenicriviroc	CCR2/5 inhibitor	Ph 3 (AURORA)	1779	NASH	**Negative**	terminated early due to lack of efficacy based on the results of Part I of the AURORA study	2021-01-13	NCT03028740

Sources: CMS (HK), company news, Cubepharma, Clinicaltrial.Gov

Our SOTP valuation

Figure 7: SOTP valuation (RMB mn)

Key assets – SBP's share	
Existing portfolio	
Anlotinib (¿5• 5 r)	18,993
Runzhong (Ÿ 5 —N)	304
Tianqing ganmei (_ ª+N5Ä# :#è)	863
Aisuping (8´9 © µ	734
TDF (P¢G® 5B0/ÅN Â W •G¥	517
Lenalidomide (›FÙ Ü70)	527
Yilunping (ÓE¤ ©	666
Tuotuo tablet (Ž Û(})	701
PD-1	707
Pipeline portfolio	
Factor VIII (¡ † µ	868
PD-L1	401
TLR-7	784
Biosimilars (+U(Ÿ2± r9¥)	2,243
COVID-19 vaccine	2,060
Other innovative pipelines	540
Other pipeline portfolio (13x NOPAT) – SBP's share	**30,981**
Other associates – SBP's share	3,559
Net cash	3,546
SOTP Valuation	**68,994**
Add：M&A premium	20,698
Equity valuation	**89,693**
TP per share (HKD)	**5.4**

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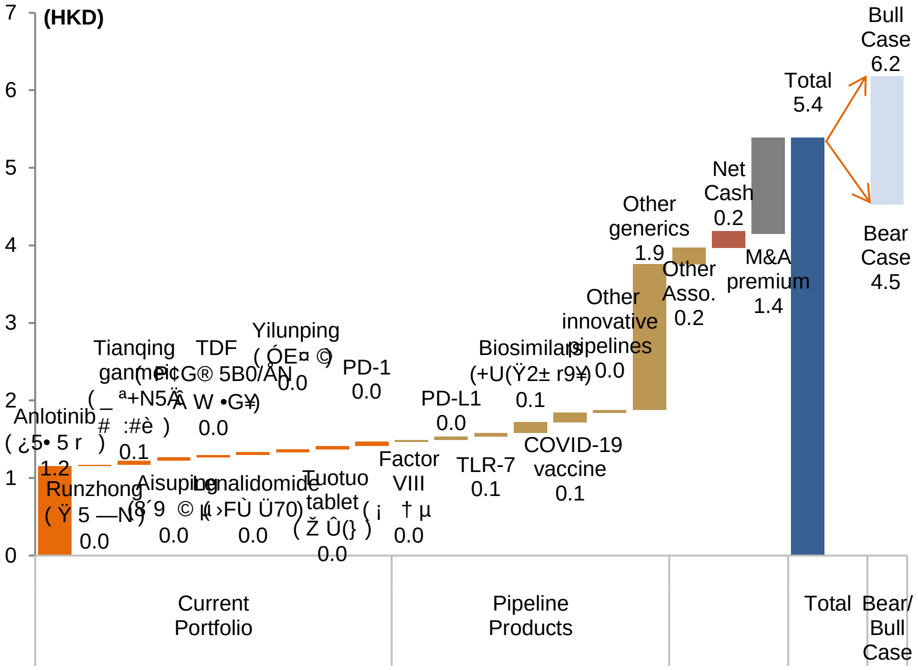
Figure 10: NAV per share breakdown & sensitivity



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Financial Summary

Balance Sheet

RMB mn	2019	2020	2021	2022E	2023E
Non-current assets	**12,601**	**24,416**	**37,040**	**38,128**	**38,777**
PP&E	6,379	6,870	7,154	7,605	7,917
Lease prepayment for LUR	1,254	1,522	1,362	1,389	1,416
Intangible assets	1,324	925	1,064	1,174	1,284
Investment properties	563	309	706	706	706
Interests in associates	808	5,051	14,266	14,766	14,966
Goodwilll	89	89	648	648	648
Others	2,183	9,651	11,840	11,840	11,840
Current assets	**24,913**	**22,794**	**23,503**	**26,013**	**29,335**
Inventories	1,659	1,880	1,938	2,054	2,327
Trade receivables	2,712	2,914	4,221	3,814	4,322
Prepayments and other receivables	6,903	2,399	1,715	1,715	1,715
Amount due from related parties	152	126	405	405	405
Assets held-for-sale	1,085	3,827	4,251	4,251	4,251
Others	491	390	405	405	405
Short-term bank deposits	1,280	635	969	969	969
Bank balances and cash	10,631	10,624	9,600	12,400	14,941
Total assets	**37,514**	**47,210**	**60,543**	**64,141**	**68,112**
Current liabilities	**8,123**	**10,944**	**15,345**	**15,706**	**15,979**
Trade and bills payables	1,809	1,948	1,693	2,054	2,327
Other payables	5,457	7,382	7,030	7,030	7,030
Income tax payable	190	61	101	101	101
ST bank debt	667	1,553	6,521	6,521	6,521
Non-current liabilities	**8,830**	**13,847**	**7,469**	**7,469**	**7,469**
Deferred government grants	481	608	674	674	674
Deferred tax liabilities	423	172	882	882	882
LT bank loans	7,885	6,922	641	641	641
Others	41	265	320	320	320
Shareholders' funds	**14,949**	**16,747**	**30,291**	**32,269**	**34,531**
Minorities	**5,612**	**5,672**	**7,438**	**8,697**	**10,132**
Total liability & equity	**37,514**	**47,210**	**60,543**	**64,141**	**68,112**

Cashflow Statement

RMB mn	2019	2020	2021E	2022E	2023E
Cash flow from operating	**5,071**	**5,110**	**5,187**	**6,593**	**6,314**
Pretax profit	5,691	5,013	18,573	6,660	7,208
Operating profit before WC changes	6,792	6,023	6,432	7,211	8,170
Net working capital change	(279)	261	(339)	651	(508)
Income tax paid	(1,102)	(959)	(727)	(966)	(1,045)
Interest paid	(340)	(215)	(180)	(303)	(303)
Cash flow from investing activities	**(3,911)**	**(7,846)**	**(2,516)**	**(1,335)**	**(1,307)**
Purchase of PPE & land use rights	(1,449)	(1,323)	(1,582)	(1,500)	(1,500)
Purchase of intangible assets	(284)	(435)	(180)	(47)	(47)
Purchase/disposal of JV&Asso.	(284)	(4,197)	(959)	0	0
Short-term investment, net	(2,303)	(4,007)	(4,362)	-	-
Interest received	246	194	162	212	240
Dividend received from an associate	299	9	4,018	-	-
Others	(135)	1,914	387	-	-
Cash flow from financing	**3,140**	**2,448**	**(3,046)**	**(2,458)**	**(2,465)**
Dividends	(820)	(1,187)	(938)	(1,618)	(1,508)
Dividends Paid To MI	(1,201)	(1,528)	(413)	(839)	(957)
Bank borrowings, net	5,199	(222)	(1,296)	-	-
Convertible bonds	-	5,612	-	-	-
Others	(4)	(4)	(4)	-	-
Beginning cash	**6,235**	**10,631**	**10,624**	**9,600**	**12,400**
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End cash	**10,631**	**10,624**	**9,600**	**12,400**	**14,941**

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Profit & Loss Statement

RMB mn	2019	2020	2021	2022E	2023E
Consolidated revenue	**24,234**	**23,647**	**26,861**	**29,340**	**33,246**
Cost of goods sold	(4,926)	(5,182)	(5,332)	(5,868)	(6,649)
Gross profit	**19,308**	**18,465**	**21,529**	**23,472**	**26,597**
Other income	605	1,047	907	880	997
(–) Total SG&A expense	**(11,797)**	**(11,629)**	**(12,704)**	**(13,700)**	**(15,536)**
Administrative expenses	(2,477)	(2,656)	(2,185)	(2,404)	(2,736)
Selling and distribution costs	(9,320)	(8,973)	(10,518)	(11,296)	(12,800)
R&D expenses	**(2,564)**	**(2,738)**	**(4,644)**	**(4,401)**	**(4,987)**
Profit from JV&Asso.	**111**	**(3)**	**13,631**	**500**	**200**
EBIT	**5,663**	**5,142**	**18,719**	**6,751**	**7,272**
EBITDA	**7,108**	**6,797**	**19,532**	**7,711**	**8,370**
(+/–) Finance expense, net	28	(129)	(147)	(91)	(63)
(+/–) Other gains/losses	-	-	-	-	-
Profit before tax	**5,691**	**5,013**	**18,573**	**6,660**	**7,208**
(–) Tax	(903)	(672)	(1,958)	(966)	(1,045)
Net profit	**4,788**	**4,341**	**16,615**	**5,694**	**6,163**
(+/–) Minority interest	(2,026)	(1,570)	(2,006)	(2,098)	(2,393)
Attributable net profit	**2,762**	**2,771**	**14,608**	**3,597**	**3,770**
Adjusted underlying profit	**3,125**	**3,114**	**2,931**	**3,147**	**3,590**
EPS fully diluted (RMB)	**0.15**	**0.12**	**0.10**	**0.16**	**0.19**
EPS fully diluted (HKD)	**0.17**	**0.14**	**0.12**	**0.19**	**0.22**
DPS (HKD)	0.08	0.08	0.08	0.08	0.08

Notes: *derived from reported net profit after excluding the impact of amortization expenses arising from the acquisition of 24% interests of Beijing Tide in 2018

Financial Ratios

	2019	2020	2021E	2022E	2023E
Growth					
Consolidated revenue	16%	-2%	14%	9%	13%
Gross profit	16%	-4%	17%	9%	13%
Adjusted net profit	12%	0%	-6%	7%	14%
Profitability					
Gross margin	80%	78%	80%	80%	80%
Adj. net profit margin	13%	13%	11%	11%	11%
ROE (year-end)	18%	14%	6%	10%	10%
ROA	7%	6%	24%	6%	6%
Efficiency					
Inventory days	(106)	(125)	(131)	(124)	(120)
Accounts receivable days	42	43	48	50	45
Accounts payable days	(135)	(132)	(125)	(117)	(120)
Cash cycle days	71	51	42	42	45
Liquidity					
FCF (HKD mn)	3,337	3,352	3,425	5,046	4,767
Net gearing (%)	(24)	(5)	(8)	(14)	(19)

Investment Ratings

Industry Rating	Definition
OVERWEIGHT	Expect sector to outperform the market over the next 12 months
NEUTRAL	Expect sector to perform in-line with the market over the next 12 months
UNDERWEIGHT	Expect sector to underperform the market over the next 12 months

Company Rating	Definition
BUY	Expect stock to generate 10%+ return over the next 12 months
HOLD	Expect stock to generate +10% to -10% over the next 12 months
SELL	Expect stock to generate loss of 10%+ over the next 12 months

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