Shanghai Henlius Biotech, Inc. (2696 HK)

Affordable innovation for global market

- **Fast-growing mAb and biosimilar market in China.** According to Frost & Sullivan, China's mAbs market is expected to grow at a 57.9% CAGR, from RMB16bn in 2018 to RMB156.5bn in 2023E. At the same time, China's biosimilars market is projected to grow at 74.2% CAGR in 2018-23E, from RMB1.6bn in 2018 to RMB25.9bn in 2023E. Henlius focuses on antibody drug development and rides on the booming biologics market in China.
- **Rich late-phase pipeline products.** Henlius develops both biosimilar and bio-innovative drugs with a strong pipeline of over 20 antibody drugs and 31 IND approvals in the field of oncology and autoimmune diseases. Henlius obtained the first biosimilar approval in China, HLX01-NHL, in Feb 2019. Besides, it has three biosimilars at near-commercial stage with high visibility, including HLX02 and HLX03 under priority review, HLX04 and HLX01-RA in Phase 3 clinical trials.
- **Industry-leading manufacturing capacity.** Henlius currently has a sizable biological manufacturing capacity of 14,000L, which is one of the largest capacities among domestic biopharmaceutical companies. A new manufacturing facility in Songjiang, Shanghai is under construction.
- **Well-established commercial capability.** Henlius will sell products through both in-house marketing team and sales force of its parent company, Fosun Pharma. Henlius has entered into commercial cooperation with Fosun Pharma and Jiangsu Wanbang (a subsidiary of Fosun Pharma) regarding HLX01 and HLX03, respectively. Henlius will leverage Fosun Pharma's strong commercial expertise in China to ramp up sales fast.
- **Risk-adjusted revenue to be RMB167mn/ RMB666mn/ RMB1,448mn in FY19E/20E/21E and profitable year to be 2021E.** Risk-adjusted revenue will be driven by HLX01 and three biosimilars at late development stage. We forecast net loss of RMB319mn/ RMB171mn in FY19E/20E and expect Henlius to record net profit of RMB198mn in FY21E.
- **Initiate BUY with TP of HK$61.12.** We derive TP of HK$61.12 based on 12-year risk-adjusted DCF valuation (WACC: 10.03%, terminal growth rate: 4.0%).
- **Catalysts:** 1) Earlier-than-expected launch of products in pipeline, 2) stronger-than-expected sales from newly launched product, 3) positive outcome of clinical trial data.

Earnings Summary

(YE 31 Dec)	FY17A	FY18A	FY19E	FY20E	FY21E
Revenue (RMB mn)	**34**	**7**	**167**	**666**	**1,448**
YoY growth (%)	*N/A*	*-78%*	*2149%*	*299%*	*117%*
Net profit (RMB mn)	**(271)**	**(494)**	**(319)**	**(171)**	**198**
YoY growth (%)	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
EPS (RMB)	**(0.77)**	**(1.16)**	**(0.59)**	**(0.32)**	**0.37**
Change (%)	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
ROE (%)	**N/A**	**N/A**	**N/A**	**N/A**	**4.6**
ROA (%)	**N/A**	**N/A**	**N/A**	**N/A**	**3.5**
Net gearing (%)	**112.9%**	**Net cash**	**Net cash**	**Net cash**	**Net cash**
Current ratio (x)	**0.2**	**2.0**	**5.9**	**3.5**	**2.2**

Source: Company data, CMBIS estimates

BUY (Initiation)

Target Price	**HK$61.12**
Up/Downside	**+38.1%**
Current Price	**HK$44.25**

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Mkt. Cap. (HK$ mn)	24,050
Avg. 3mths t/o (HK$ mn)	N/A
52W High/Low (HK$)	50.90/39.70
Total Issued Shares (mn)	163

Source: Bloomberg

Shareholding Structure

Fosun Pharma	53.76%
Management	11.35%
Institution investors	23.02%
Free float	11.71%

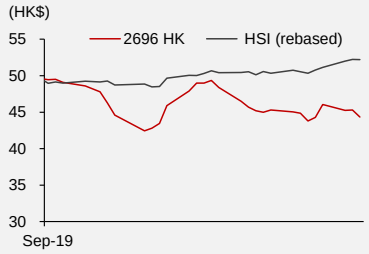
Source: Bloomberg

Share performance

	Absolute	Relative
1-mth	-0.9%	-7.6%
3-mth	N/A	N/A
6-mth	N/A	N/A

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: Ernst & Young
Web-site: www.henlius.com

Contents

Investment Thesis

Shanghai Henlius Biotech, Inc. ("Henlius") is an integrated biopharmaceutical company with strong capabilities in biological drugs R&D, production and sales. It focuses on developing biosimilars and bio-innovative drugs. Henlius got the first approval of monoclonal antibody (mAb) biosimilar in China, HLX01. It has in-house developed over 20 biologic drug candidates and immuno-oncology combination therapies, including 1) HLX01, which obtained launching approval from the NMPA on 22 Feb 2019, becoming the first-to-market mAb biosimilar in China, 2) HLX02 with NDA filed to NMPA and EMA, HLX03 with NDA filed to NMPA, 3) HLX01 for RA, HLX04 and five immuno-oncology combination therapies in Phase 3 clinical trials and six mAb candidates undergoing Phase 1/2 clinical trials , and 4) 31 IND approvals received from different jurisdictions.

Riding on the fast-growing mAb and biosimilar market in China

According to Frost & Sullivan (F&S), China's biologics will grow at 19.6% CAGR in 2018-23E, rising from RMB262.2bn to RMB641.2bn. China's mAbs sales only accounted for 6.1% of overall biologics market in 2018, vs. 55.3% for global market, representing a sizable market potential in China. China mAbs market is expected to grow at 57.9% CAGR in 2018-23E, from RMB16bn in 2018 to RMB156.5bn in 2023E, driven by new treatments and rapid growth of mAb biosimilars. At the same time, China's biosimilars market is expected to grow at 74.2% CAGR in 18-23E, from RMB1.6bn in 2018 to RMB25.9bn in 2023E, due to 1) the establishment of biosimilars guidelines, 2) the inclusions of biological drugs into the NRDL and potential more inclusions through price negotiations, and 3) near-term and medium-term patent expiration of a larger number of "blockbuster" biologics.

High pipeline visibility with one product launched and three in late-stage

HLX01 (rituximab biosimilar), the first approved biosimilar in China

HLX01 filed NDA in 2017 and received launching approval from NMPA on 22 Feb 2019. As of Nov 2019, HLX01 has been successfully added to several Provincial reimbursement drug lists at a negotiated price range of RMB1,398-1,648 per 100mg/via, implying over 30% discount to the originator. According to F&S, rituximab recorded China sales of RMB2.5bn in 2018 and is expected to grow at 21.9% CAGR in 2018-23E to RMB6.8bn in 2023E, mainly driven by more affordable treatments. Henlius authorized the commercial right of HLX01 to Fosun Pharma. Since the launch of HLX01 in late May 2019, HLX01 realized revenue of RMB13.3mn in 1H19 in accordance to the profit-sharing arrangement with Fosun Pharma. As of 30 Jun, 2019, Henlius has delivered 20,638 vials of HLX01 to Fosun Pharma. We expect HLX01 will gain more market share, owing to 1) the first mover advantage, 2) Fosun Pharma's strong sales expertise and excellent market access, 3) price advantages over the originator, and 4) future approval for a new indication, RA.

Three biosimilars in late stage

Henlius has other three biosimilars in late stages, namely HLX02 (Herceptin biosimilar), HLX03 (Humira biosimilar) and HLX04 (Avastin biosimilar). The Company expects to launch these biosimilars in 2020-2021E.

HLX02 (Herceptin biosimilar) - Henlius conducted global clinical trials for HLX02 and has filed NDA to NMPA in Apr 2019 for treatment of HER2+eBC, HER2+mBC and HER2+mGC and filed NDA to EMA in Jun 2019. According to F&S, HLX02 is the first biosimilar developed in China that has conducted a global Phase 3 clinical trial across multiple continents (sites in China, Philippines and Europe) and has the potential to become the first PRC-developed mAb biosimilar in EU and the first-to-market trastuzumab biosimilar in China. Herceptin was added to 2017 NRDL and 2018 NEDL. According to F&S, China's trastuzumab market is expected to grow at 23.9% CAGR in 2018-23E to ~RMB9.4bn in 2023E thanks to better affordability.

HLX03 (Humira biosimilar) - Henlius has filed NDA of HLX03 to the NMPA in 1Q19 for treatment of PS, RA and AS. Henlius plans to commercialise HLX03 as an affordable alternative to Humira in the PRC, where there is a significant population of RA, PS and AS patients who do not have access to Humira due to economic reasons. According to F&S, in 2018, Humira was the highest-selling drug globally with US$20.5bn global sales, while its sales in China was only RMB400mn, limited by affordability. Sales from China accounts for only 0.2% of Humira's global sales, while China's RA, PS and AS patients accounts for ~9% of global patient pool. According to F&S, China's adalimumab market is expected to grow at a 74.6% CAGR in 2018-23E to ~RMB5.8bn in 2023E.

HLX04 (Avastin biosimilar) - Henlius is conducting a Phase 3 clinical trial on HLX04 for mCRC and is expected to file NDA to the NMPA in 2020E for treatment of mCRC and unresectable, locally advanced, recurrent or metastatic nsNSCLC. HLX04 could be the first Avastin biosimilar in China with Phase 3 clinical data on mCRC patients, while other competitors focus on the indication of nsNSCLC. Besides, Henlius has also submitted IND applications of HLX04 for the indications of wAMD and DR. Furthermore, Henlius is developing a combination therapy of HLX04 + HLX10, which will help increase sales for HLX04. According to F&S, China's bevacizumab market is estimated to grow at 32.7% CAGR from RMB3.2bn in 2018 to RMB13.1bn in 2023E.

Robust pipeline in innovative therapies

In addition to biosimilars, Henlius has developed a portfolio of innovative mAbs which have entered Phase 1b/2 clinical studies, including HLX06 (a novel VEGFR2 inhibitor), HLX07 (an EGFR inhibitor), HLX10 (a novel PD-1 inhibitor), HLX20 (a novel PD-L1 inhibitor) and HLX22 (a HER2 inhibitor). Besides, its combination therapy (HLX04 + HLX10) has entered into Phase 2/3 clinical trials, which is the first combo trial on bevacizumab and PD-1 inhibitor in China. Another combination therapy (HLX07 + HLX10) has filed IND application. Henlius will explore more combo therapies using its biosimilars or innovative drugs with PD-1 or PD-L1.

Further strengthening its industry-leading capacity

Henlius has its own manufacturing facility for mAb products in Xuhui, Shanghai. The Xuhui Facility currently has six 2,000L single-use bioreactors and four 500L single-use bioreactors, amounting to total capacity of 14,000L capacity, which is one of the largest capacities among domestic biopharmaceutical companies. A new manufacturing facility in Songjiang, Shanghai is under construction which will further strengthen the Company's commercial capability.

Well-established commercialization capabilities

Henlius aims to provide high-quality, affordable and innovative drugs to patients worldwide. In China, Henlius will sell products through in-house marketing team and also leverage the strong sales expertise of Fosun Pharma, its parent company. Henlius has entered into commercial cooperation with Fosun Pharma and Jiangsu Wanbang with regard to the products of HLX01 and HLX03 respectively.

For overseas markets, Henlius has partnered with global pharmaceutical companies, such as Biosidus, Accord, Cipla and Jacobson, KG Bio, etc. These arrangements enable Henlius to leverage its partners' competitive sales capabilities in local markets.

Risk-adjusted revenue expected to be RMB167mn/ RMB666mn/ RMB1,448mn in FY19E/20E/21E and profitable year to be 2021E

HLX01 will generate revenue since 2019. HLX02 and HLX03 have filed NDAs and are assumed to be approved in 2020E with probability of success (PoS) of 90%. HLX04 is in phase 3 trial and we expect it to file NDA in 2020E and to be approved in 2021E with PoS of 72%.

We forecast risk-adjusted revenue of RMB167mn/ RMB666mn/ RMB1,448mn in FY19E/20E/21E, driven by sales from HLX01 and other three biosimilars at late stage. We forecast net loss of RMB319mn/ RMB171mn in FY19E/20E and net profit of RMB198mn in FY21E. Henlius is expected to turn profitable from 2021E.

Initiate BUY with TP of HK$61.12

As Henlius is a pre-revenue biotechnology company, DCF would be a suitable valuation method. We derive TP of HK$61.12 based on a 12-year DCF valuation (WACC: 10.03%, terminal growth rate: 4.0%).

Investment risks

1) Limited operating history, which may continue to incur losses in the future;
2) Drugs in clinical development involves a lengthy and expensive process with no assured outcome;
3) No track record of successful commercialisation, which makes it difficult to evaluate future prospects;
4) Medical cost control may lead to further price cut;
5) Limited experience in manufacturing biologics drugs on commercial scale;
6) Fierce competition from peers in China and overseas.

Company Overview

Henlius Biotech Co., Ltd ("Henlius") focus on development, production and sales of biological products. Established in 2010 and Listed in HKEX in Sep 2019, Henlius is a non-wholly owned subsidiary of Fosun Pharma (2196 HK) with R&D centers in Shanghai, Taipei and California. Henlius has built up a pipeline of over 20 antibody drug candidates with 31 IND approvals. As a leading biopharmaceutical company in China, Henlius launched the first biosimilar product in accordance with China's Biosimilar Guidelines.

Henlius aims to become a world-class biopharmaceutical company and to provide affordable drugs to patients in China and worldwide. Its co-founder, Dr. Scott Liu and Dr. Wei-Dong Jiang possess ~25-year experiences in R&D. As of 30 Jun 2019, Henlius has 874 staff, of which Research & Development is the biggest division with 260 staff.

Figure 1: Key milestones of Henlius

Year	Event
2010	Established in Shanghai.
2011	Filed an IND application with the NMPA for HLX01 for non-Hodgkin lymphoma (NHL).
2012	Filed an IND application with the NMPA for HLX02 for breast cancer.
2013	Filed an IND application with the NMPA for HLX03 for rheumatoid arthritis.
2014	Taiwan Henlius became a non-wholly owned subsidiary of the Company, primarily engaged in mid-to-late stage research, enabling the Company to access the deep biotech talent pool in Taiwan. Received approval from the NMPA to conduct Phase 1 clinical trials for HLX01 in NHL. Commenced the construction of the Xuhui Facility in Dec 2014. Filed an IND application with the NMPA for HLX04 for metastatic colorectal cancer.
2015	Hengenix, a wholly-owned subsidiary of the Company, was incorporated in California, United States, focusing on early stage R&D as well as providing the Company with better access to the latest developments in the monoclonal antibodies (mAb) market and cutting-edge technologies. Filed an IND application with the NMPA for HLX07 for solid tumours.
2016	Received approval from the NMPA to conduct Phase 1 clinical trials for 1) HLX02 for gastric cancer, and 2) HLX04 for non-squamous, non-small cell lung cancer (nsNSCLC).
2017	The Company obtained the Drug Manufacturing Certificate for HLX01 from NMPA Shanghai Bureau and received the Notice on Acceptance of Drug Registration Application from the NMPA for HLX01 for NHL. Filed an NDA with the NMPA for HLX01 for NHL. Submitted an IND application with the NMPA for HLX10 for solid tumours.
2018	Acquired the remaining equity interest in Taiwan Henlius and Taiwan Henlius became a wholly-owned subsidiary of the Company.
2019	Filed NDA for HLX03 in Jan 2019. HLX01 for NHL formally approved by NMPA, the first mAb biosimilar in China. Filed NDA for HLX02 to NMPA in Apr 2019. HLX01's first prescription issue on 5 May, 2019. Filed NDA for HLX02 to EMA in Jun 2019. HLX03 completed phase 3 clinical trial in Jul 2019. HLX10+Chemo completed first patient dosing of Phase 3 trial study.

Source: Company data, insight and CMBIS

Rich pipeline with over 20 drug candidates

Henlius has established a comprehensive product pipeline of both biosimilars and bio-innovative drugs. It had developed in-house over 20 biologic drug candidates and immuno-oncology combination therapies, including 1) HLX01, which obtained launching approval from the NMPA on 22 Feb 2019, becoming the first-to-market mAb biosimilar in China, 2) HLX02 which has filed NDA to NMPA and EMA, HLX03 with NDA filed to NMPA, 3) HLX01 for RA, HLX04 and five immuno-oncology combination therapies in Phase 3 clinical trials and six mAb candidates undergoing Phase 1/2 clinical trials , and 4) 31 IND approvals received from different jurisdictions.

Figure 2: Pipeline focusing on biosimilars and novel biologics

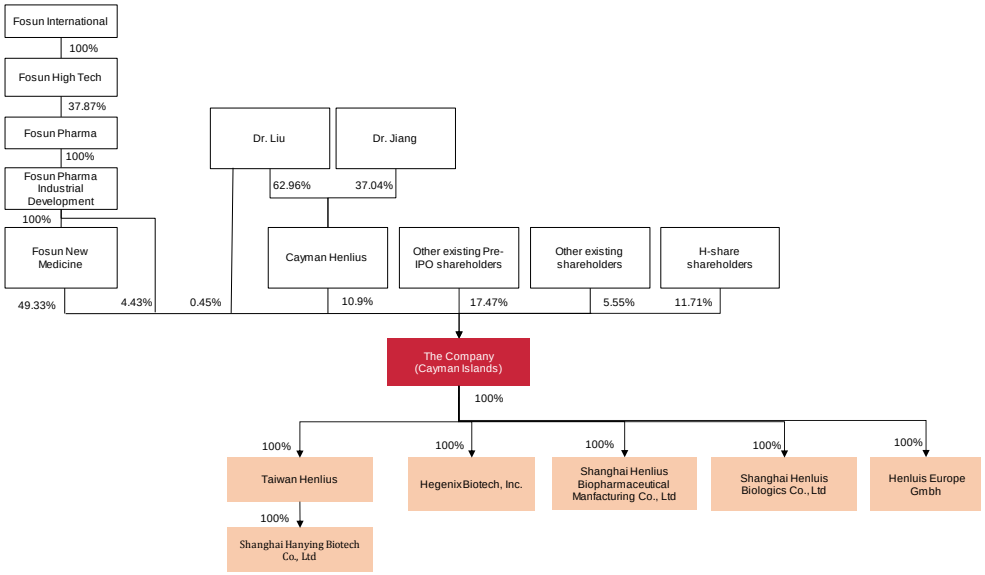
	Product (Reference Drug)	Target	Indication	Commercial Rights	Partner (Territory)	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	NDA approved
Biosimilars	HLX01 (MabThera)	CD20	NHL	Worldwide	FOSUN PHARMA (China); BIOSIDUS (South America)							
	HLX02 (Herceptin)	HER2	BC/mGC	Worldwide	accord Cipla Jacobson (Europe, MENA and CIS; APAC and South America; Hong Kong and Macau)							
	HLX03 (Humira)	TNF-α	PS/RA/AS	Worldwide	FOSUN PHARMA (China)							
	HLX04 (Avastin)	VEGF	mCRC/nsNSCLC	Worldwide								
	HLX05 (Erbitux)(9)	EGFR	mCRC/SCCHN	Worldwide (ex-China)	Bingze	China Rights Licesed out						
	HLX12 (Cyramza)	VEGFR2	Solid tumours	Worldwide								
	HLX11 (Perjeta)	HER2	BC	Worldwide								
	HLX14 (Xgeva)	RANK ligand	Solid tumours	Worldwide								
	HLX13 (Yervoy)	CTLA-4	Solid tumours	Worldwide								
	HLX15 (Darzalex)	CD-38	Multiple Myeloma	Worldwide								
Bio- Innovative Portfolio	HLX01	CD20	RA	Worldwide								
	HLX04	VEGF	w AMD/DR	Worldwide								
	HLX07	EGFR	Solid tumours	Worldwide		IND approved in the US, Taiwan, Mainland China						
	HLX06	VEGFR2	Solid tumours	Worldwide		IND approved in the US, Taiwan, Mainland China						
	HLX10	PD-1	Solid tumours	Worldwide	Kalbe Genexine Biologics	IND approved in the US, Taiwan, Mainland China						
	HLX20	PD-L1	Solid tumours	Worldwide		IND approved in the US, Taiwan, Mainland China						
	HLX22	HER2	Solid tumours	Worldwide		In-Licensed						
	HLX55	cMET	Solid tumours	Asia		In-Licensed						
	HLX56	DR	Solid tumours	The greater China		In-Licensed						
	HLX09	CTLA-4	Solid tumours	Worldwide								
	HLX23	CD73	Solid tumours	Worldwide								
	HLX24	CD47	Solid tumours	Worldwide								
	HLX26	LAG3	Solid tumours	Worldwide								
	HLX59	CD27	Solid tumours	Worldwide								
	HLX51	OX40	Solid tumours	Worldwide								
	HLX52	TIM-3	Solid tumours	Worldwide								
	HLX53	TIGIT	Solid tumours	Worldwide								
	HLX58	Claudin 18.2	Solid tumours	Worldwide								
	HLX63	GPC3	Solid tumours	Worldwide								
Combo Therapy	HLX04 + HLX10	VEGF + PD-1	nsNSCLC	Worldwide								
	HLX04 + HLX10	VEGF + PD-1	HCC	Worldwide								
	HLX07 + HLX10	EGFR + PD-1	SCCHN	Worldwide								
	HLX10 + Chemo	PD-1	mESCC	Worldwide							Core products	
			sqNSCLC	Worldwide								
			ES-SCLC	Worldwide								
			GC	Worldwide								

Source: Company data, CMBIS

Shareholding structure

Henlius was listed on the main board of Hong Kong Stock Exchange on 25 Sep 2019. To date, Fosun Pharma held ~53.76% stake in Henlius. Henlius conducted three rounds of financing before IPO. Its pre-IPO investors include Joyful Ascent Limited (Jacobson Pharma (2633 HK)'s wholly-owned subsidiary), Fullgoal China Access RQFII Fund SPC, CICC Alternative Investment Holding Limited, etc.

Figure 3: Shareholders structure post IPO, as of 24 Sep 2019



Notes:

(1) Other existing Pre-IPO Investors are existing Pre-IPO Investors other than Fosun Pharma Industrial Development.

(2) Other existing Shareholders are companies whose beneficial owners are employees of the Company, comprising Shanghai Guoyou, Shanghai Guohong, Shanghai Guozhi, Shanghai Guoyun and HenLink.

Source: Company data, CMBIS

High pipeline visibility with rich late-stage assets

Biosimilars are referred to biological drugs which are designed to have the same amino acid sequence and the equivalent (but not identical or clinical better) active properties as compared to reference drugs that have already received marketing approvals. China's biosimilars market is expected to grow at 74.2% CAGR in 2018-23E, from RMB1.6bn in 2018 to RMB25.9bn in 2023E, due to 1) the establishment of biosimilars guidelines, 2) the inclusions of biological drugs into the NRDL and potential more inclusions through price negotiations, and 3) near-term and medium-term patent expiration of a larger number of "blockbuster" biologics.

Henlius has 10 mAb biosimilars in the pipeline. Of China's five largest biosimilars, Henlius developed four, with one received marketing approval and three in late stage, namely HLX01 (rituximab), HLX02 (trastuzumab), HLX03 (adalimumab) and HLX04 (bevacizumab).

HLX01 (rituximab biosimilar), expect RMB1.47bn peak sales from NHL indication

HLX01 is a rituximab biosimilar and obtained launching approval from NMPA in Feb 2019 for the non-Hodgkin lymphoma (NHL) indication, making it the first biosimilar drug approved in China in accordance with the Biosimilar Guidelines. Henlius is also conducting a Phase 3 clinical trial on HLX01 for a new indication of rheumatoid arthritis (RA).

In Nov 2019, Henlius has entered into cooperation with Ascentage Pharma (6855 HK) to co-develop the combination therapy of HLX01 and APG-2575, a novel Bcl-2 selective inhibitor, for the treatment of chronic lymphocytic leukemia (CLL) in China.

Global top selling drug. Originally developed by IDEC Pharmaceuticals and Genentech, Rituximab is a monoclonal anti-body that selectively binds to protein CD20 of B cells, which triggers cell death. Rituximab was firstly launched in the US in 1997. Major patents have expired in most regions, including patent expiration in Europe in 2013 and in the US in 2016. Globally, rituximab was approved for various indications, including first-or second-line therapies of NHL, chronic lymphocytic leukaemia, RA, granulomatosis with polyangiitis, microscopic polyangiitis and moderate-to-severe pemphigus vulgaris in overseas market. In China, MabThera was approved for only three indications, 1) CD20-positive DLBCL, 2) relapsed or refractory follicular central lymphoma and 3) previously-untreated CD20-positive stage III-IV follicular lymphoma. As per Roche's annual report, in 2018, rituximab was global top 8 selling drug, generating global sales of CHF6.8bn in 2018 vs CHF7.4bn in 2017. Sales decline was caused by fierce competition from rituximab biosimilars, mainly from European market. As per F&S, China rituximab sales was ~RMB2.5bn sales in 2018.

Biosimilars to fast substitute the original drug. According to F&S, new NHL cases in China is projected to be ~88,100 in 2018. Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of NHL in China, accounting for ~46% of overall NHLs. Rituximab was added to NRDL in 2017 and NEDL in 2018. According to our estimates, China's penetration rate of rituximab on DLBCL and FL was around 73% in 2018. As the first to market rituximab biosimilar, we believe HLX01 will fast substitute to MabThera thanks to 1) price advantages over the originator, 2) good reimbursement coverage for HLX01.

Figure 4: HLX01 sales forecasts – NHL indication

HLX01-NHL		2018A	2019E	2020E	2021E	2022E	2023E
Non-Hodgekins Lymphoma (NHL) new cases	**'000**	**88**	**90**	**92**	**95**	**97**	**99**
as % of total lymphoma	*%*	*88%*	*87%*	*87%*	*86%*	*86%*	*85%*
Newly diagnosed patients	'000	62	64	67	69	71	74
% diagnosis rate	*%*	*70%*	*71%*	*72%*	*73%*	*74%*	*75%*
relapsed (5yr cumulative) patient	'000	31	32	33	34	36	37
Total NHL patient pool	**'000**	**93**	**96**	**100**	**103**	**107**	**111**
Diffuse large B-cell lymphoma (DLBCL)	'000	43	44	46	48	49	51
as % of NHL	*%*	*46%*	*46%*	*46%*	*46%*	*46%*	*46%*
Follicular lymphoma (FL)	'000	9	10	10	10	11	11
as % of NHL	*%*	*10%*	*10%*	*10%*	*10%*	*10%*	*10%*
CD20+ DLBCL/FL patients	**'000**	**49**	**51**	**53**	**55**	**57**	**59**
CD20+ DLBCL/FL patients on rituximab	**000**	**40**	**38**	**40**	**42**	**44**	**46**
Penetration rate of CD20+ DLBCL/FL patients on rituximab	*%*	*73%*	*74%*	*75%*	*76%*	*77%*	*78%*
NHL patients on HLX01	**000**	**-**	**6**	**12**	**15**	**18**	**21**
HLX01-NHL patient share	*%*	*0%*	*15%*	*30%*	*35%*	*40%*	*45%*
Off -label patients on HLX01	**000**	**0**	**0**	**1**	**2**	**2**	**2**
Total patients on HLX01	**000**	**0**	**6**	**13**	**16**	**20**	**23**
Price of MabThera	RMB	2,418	2,297	1,953	1,913	1,875	1,838
Price erosion	*%*	-	*-5%*	*-15%*	*-2%*	*-2%*	*-2%*
ASP of HLX01,100mg/vial	RMB	-	1,398	1,367	1,339	1,313	1,286
Price discount to originator	*%*		*39%*	*30%*	*30%*	*30%*	*30%*
# of vials per treatment	vial	34	36	42	49	49	56
Total volume	000	-	207	504	720	864	1,166
Total sales (hospital-level)	RMB mn	-	290	688	964	1,134	1,500
Total sales (ex-factory)	**RMB mn**	**-**	**269**	**675**	**946**	**1,112**	**1,471**
MabThera full-course treatment cost	RMB 000	135	129	109	107	105	103
HLX01 full-course treatment cost	RMB 000	-	78	77	75	74	72

Source: F&S, PDB, CMBIS estimates

Competitors at late stage. There are six rituximab biosimilars in late phase of development, including SinoCelltech's SCT400 (licensed-out to CSPC in Oct 2018), Innovent Biologics (1801 HK)'s IBI301 and Hisun's Chimeric Anti-CD20 mAb, Genor Biopharma's GB241, CTTQ's TQB2203 and Hualan Bio's HL03. HLX01 is the first-to-market rituximab biosimilar in China. **As a front-runner, we estimate HLX01 to penetrate to 5,697/ 11,992 patients in 2019E/20E with 15%/ 30% patient share in 2019E/20E.**

Figure 5: Key rituximab biosimilars in late stage of development in China

Reference Drug	Indication	Biosimilar	Key players	Regulatory filing status as at 31/3/2019	Relevant filing/ approval date	Approved date	Marketing partner
MabThera (rituximab, Roche)	**NHL**	**HLX01**	**Henlius**	**NDA approved**	**Oct-17**	**Feb-19**	**Fosun Pharma (2196 HK)**
	NHL	SCT400	SinoCelltech	Phase 3	Jun-16	N/A	CSPC (1093 HK)
	NHL	IBI301	Innovent Biologics	NDA filed	Aug-16	N/A	Eli Lilly
Expiry of major patents	NHL	Chimeric Anti-CD20 mAb	Zhejiang Hisun and Mabworks Biotech	Phase 3	Jul-18	N/A	Hisun (600267 CH)
	NHL	GB241	Genor Biopharma	Phase 3	Nov-18	N/A	
PRC:2013	NHL	TQB2203	CTTQ	Phase 3	Dec-18	N/A	
US: 2016	NHL	HL03	Hualan Bio	Phase 3	Apr-19	N/A	
EU:2013	**RA**	**HLX01**	**Henlius**	**Phase 3**	**Aug-18**	**NA**	**Fosun Pharma (2196 HK)**

Source: Company data, CMBIS

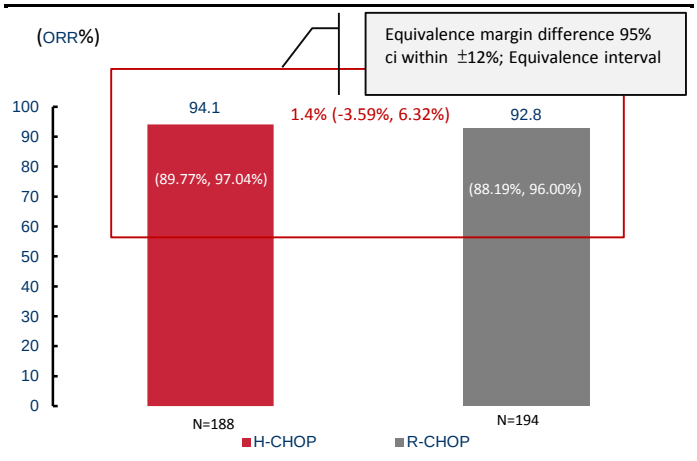
Figure 6: Rituximab biosimilars approved by FDA/ EMA

Biosimilar	Key players	Status	Approved date
Truxima	Celltrion and Teva	NDA approved	US (Nov-18)/ EU (Feb-17)
Rixathon	Sandoz and Novartis	NDA Approved	EU (Jun-17)

Source: Company data, CMBIS

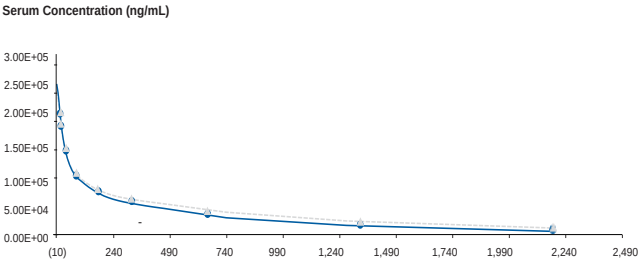
Achieved bioequivalence between HLX01 and MabThera. NMPA approved HLX01 for treatment of NHL based on a multi-centre, randomised, double-blinded, parallel Phase 3 study on 400 subjects, which showed bioequivalence between HLX01 combined with CHOP and MabThera combined with CHOP. The primary endpoint of the study is objective response rate (ORR). ORR rates of H-CHOP and R-CHOP were 94.1% and 92.8% with P value of 0.608. In a Phase 1b trail (n=80), HLX01 showed the same pharmacokinetic (PK) profile as MabThera. Both study group established equivalent PK profiles in $AUC_{0\text{-}91D}$. There was no statistically significant difference in the incidence and severity of adverse effects between HLX01 and MabThera.

Figure 7: ORR rate of HLX01 is statistically equivalent to MabThera



Source: Company data, CMBIS

Figure 8: PK profile of HLX01 is statistically equivalent to MabThera



Parameter	Geometric Mean HLX01	Geometric Mean MabThera	Geometric Ratio (HLX01/MabThera)	90%CI (HLX01/MabThera)
$AUC_{0\text{-}91D}$ ($x10^5$ h*ng/mL)	637.93	711.90	89.61%	80.56%-99.67%

Source: Company data, CMBIS

First-to-market biosimilar with huge market opportunity. Henlius started Phase 1 study for HLX01 in 2014, filed NDA in 2017 and received launching approval from NMPA in Feb 2019. MabThera costs around RMB2,400 per 100mg/vial in China. As of Nov 2019, HLX01 has been successfully added to several Provincial reimbursement drug lists at a negotiated price range of RMB1,398-1,648 per 100mg/via, implying over 30% discount to the originator. According to F&S, rituximab market size in China was RMB2.5bn in 2018 and is projected to grow at 21.9% CAGR in 2018-23E. According to the cooperation arrangement for commercialization of HLX01 between Henlius and Fosun pharma, Fosun Pharma fully reimburses the clinical trial cost of HLX01 and Henlius is responsible for the production of HLX01, while the marketing expenses are undertaken by Fosun Pharma. The net profit from HLX01 sales will be equally shared by Henlius and Fosun Pharma. Since the launch of HLX01 in late May 2019, HLX01 realized revenue of RMB13.3mn in 1H19 in accordance to the profit-sharing arrangement with Fosun Pharma. As of 30 Jun, 2019, Henlius has delivered 20,638 vials of HLX01 to Fosun Pharma.

Three biosimilars in late stage of development

Henlius has filed NDAs for HLX02 (Herceptin biosimilar) and HLX03 (Humira biosimilar), both of which are under priority review by NMAP. HLX04 (Avastin biosimilar) is in phase 3 trial.

Figure 9: Summary of Henlius' late stage biosimilar candidates

Product (Reference Drug)	Target	Indication	Commercial Rights	Partner (Territory)	Status	IND date	Expected NDA date	2018 originator's China sales	2018 originator's global sales
HLX02 (Herceptin)	HER2	BC/mGC	Worldwide	accord (Europe, MENA and CIS) Cipla (APAC and South America) Jacobson (Hong Kong and Macau) FOSUN PHARMA (China)	NDA	2015	Apr-19 in China; Jun-19 in Europe	RMB3.2bn	US$6.9bn
HLX03 (Humira)	TNF-α	PS/RA/AS	Worldwide		NDA	2015	Jan-19	RMB0.4bn	US$20.5bn
HLX04 (Avastin)	VEGF	mCRC/nsNSCLC	Worldwide		Phase 3	2015	2020E	RMB3.2bn	US$6.7bn

Source: Company data, F&S, CMBIS

HLX02 (Herceptin biosimilar), expect RMB2.74bn peak sales

Henlius filed NDA of HLX02 to NMPA in Apr 2019 for the treatment of HER2+, eBC, HER2+mBC and HER2+mGC in China, which received priority review status from NMPA. Henlius also submitted NDA of HLX02 to EMA in Jun 2019. According to F&S, HLX02 is the first biosimilar developed in China that has conducted a global Phase 3 clinical trial across multiple continents (sites in China, Philippines and Europe) and has the potential to become the first PRC-developed mAb biosimilar in EU and the first-to-market trastuzumab biosimilar in China.

Given that HLX02 is the first biosimilar developed in China to conduct a Phase 3 global clinical trial concurrently across multiple continents (sites in China, Philippines and Europe), it may become the first PRC-developed mAb biosimilar to launch in EU.

Global Top 6 selling drug. Herceptin (trastuzumab) is a HER2 inhibitor originally developed by Genentech. It initially received FDA approval in 1998 and launched to China in 2002. Herceptin was approved by FDA for indications of HER2-overexpressing (HER2+) BC and HER2+ metastatic gastric or gastroesophageal junction adenocarcinoma. In China, Herceptin has been approved for three indications, HER2+ eBC, HER2+ mBC and HER2+ mGC. Major patents have expired globally, including patent expiration in Europe in 2014 and in the US in 2019. Trastuzumab is widely regarded as the standard of care for first-line treatment of HER2+ Breast Cancer (BC). As per Roche's annual report, 2018 global sales of Herceptin amounted to CHF6.9bn (~US$6.9bn), while China sales was RMB3.2bn.

Demand surge thanks to NRDL inclusion. Herceptin was added to NRDL in 2017 and NEDL in 2018. We saw PDB sample hospital sales of Herceptin grew significantly from RMB887mn in 2017 to RMB1,310mn in 2018, up 48% YoY, driven by NRDL inclusion. The demand surge for Herceptin in China also triggered supply shortage in 2018. Roche raised production capacity after Herceptin's inclusion into NRDL. We believe the HLX02 as a Herceptin biosimilar will meet the surging demand in China.

Figure 10: HLX02-BC sales forecasts

HLX02-BC		2018A	2019E	2020E	2021E	2022E	2023E
Breast cancer new cases	**000**	**321**	**325**	**329**	**333**	**337**	**342**
Stage I-IIIa BC Patients treated with total mastectomy	'000	250	256	262	268	274	280
mBC patient pool	'000	39	36	34	31	29	27
5-year accumulated eBC relapsed patients	000	160	162	164	167	169	171
mBC+eBC+relapsed	**000**	**449**	**455**	**460**	**466**	**472**	**478**
HER2+ positive new cases	**'000**	**118**	**120**	**121**	**123**	**124**	**126**
as % of total breast cancer	*%*	*26%*	*26%*	*26%*	*26%*	*26%*	*26%*
Eligible HER2 BC Patient Pool	**000**	**96**	**100**	**103**	**107**	**111**	**116**
% diagnosed rate	*%*	*89%*	*90%*	*91%*	*92%*	*94%*	*95%*
% treatment rate	*%*	*92%*	*93%*	*94%*	*95%*	*96%*	*97%*
Patients on trastuzumab	**000**	**29**	**35**	**42**	**49**	**56**	**63**
Penetration rate	*%*	*31%*	*36%*	*41%*	*46%*	*51%*	*55%*
Patients on HLX02	**000**	**0.00**	**0.00**	**4.18**	**9.76**	**19.71**	**25.30**
HLX02-BC patient share	*%*	*0%*	*0%*	*10%*	*20%*	*35%*	*40%*
Price of Herceptin	RMB	7600	7448	7270	7125	6982	6842
ASP of HLX02, 440mg/vial	RMB	-	-	5089	4987	4887	4790
Price discount to originator	*%*	*-*	*-*	*30%*	*30%*	*30%*	*30%*
# of vial per year per patient	vial	13	13	15	15	15	15
Total volume	000	-	-	63	146	296	370
Total sales (hospital-level)	RMB mn	-	-	319	730	1445	1771
Total sales (ex-factory)	**RMB mn**	**-**	**-**	**282**	**644**	**1,275**	**1,564**
Herceptin full-course treatment cost	RMB 000	129	127	124	121	119	116
HLX02 full-course treatment cost	RMB 000	0	0	87	85	83	81

Source: F&S, PDB, CMBIS estimates

Figure 11: HLX02-GC sales forecasts

HLX02-GC		2018A	2019E	2020E	2021E	2022E	2023E
Gastric cancer new cases	**000**	**442**	**455**	**467**	**480**	**493**	**507**
Late stage patient	000	239	245	252	259	266	274
5-year accumulated eGC relapsed patients	000	71	73	75	77	79	81
Total GC patient pool	000	310	318	327	336	345	355
HER2+ postive new cases	**000**	**37**	**38**	**39**	**40**	**41**	**43**
% with HER2+	*%*	*12%*	*12%*	*12%*	*12%*	*12%*	*12%*
Eligible HER2 GC Patient Pool	**000**	**19**	**20**	**20**	**21**	**22**	**23**
% diagnosed rate	*%*	*63%*	*64%*	*65%*	*66%*	*66%*	*67%*
% treatment rate	*%*	*80%*	*80%*	*80%*	*80%*	*80%*	*80%*
Patients on trastuzumab	**000**	**6**	**7**	**9**	**10**	**12**	**13**
Penetration rate	*%*	*33%*	*38%*	*43%*	*48%*	*53%*	*58%*
Patients on HLX02	**000**	**0**	**0**	**1**	**2**	**4**	**5**
HLX02-GC patient share	*%*	*0%*	*0%*	*10%*	*20%*	*35%*	*40%*
Price of Herceptin	RMB	7600	7448	7270	7125	6982	6842
ASP of HLX02, 440mg/vial	RMB	-	-	5,089	4,987	4,887	4,790
Price discount to originator	*%*	*0%*	*0%*	*30%*	*30%*	*30%*	*30%*
# of vial per year per patient	vial	7	7	7	7	8	8
Total volume	000	-	-	6	15	31	41
Total sales (hospital-level)	RMB mn	-	-	32	74	150	196
Total sales (ex-factory)	**RMB mn**	**-**	**-**	**28**	**66**	**133**	**173**
Herceptin full-course treatment cost	RMB 000	68	67	65	64	63	62
HLX02 full-course treatment cost	RMB 000	0	0	46	45	44	43

Source: F&S, PDB, CMBIS estimates

Competition landscape. There are five competing products in late stage of development, four in Phase 3 clinical trial and Sunshine Guojian has filed new drug NDA with recombinant humanised anti-HER2 mAb in Sep 2018. By contrast, Henlius conducted head to head clinical trials for HLX02 in accordance to the Biosimilar Guidelines. HLX02 is still well-positioned to become the first-to-market real Herceptin biosimilar in China. We estimate that BC patients on HLX02 to be 4,182/ 9,756 in 2020/21E and patient share on trastuzumab to be 10%/20% and GC patients on HLX02 to be 872/ 2,024 in 2020/21E.

Figure 12: Key competitors to trastuzumab biosimilars in late stage in China

Reference Drug	Indication	Biosimilar	Key players	Regulatory filing status as at 31/3/2019	Relevant filing/ approval date
Herceptin (trastuzumab, Roche)	**BC/ mGC**	**HLX02**	**Henlius**	**NDA accepted**	**Apr-19**
	BC	Trastuzumab Biosimilar	Anhui Anke Biotechnology	Phase 3	May-19
	BC	GB221	Genor Biopharma	Phase 3	Sep-16
Expiry of major patents PRC:2018 US: 2019 EU: 2014	BC	Trastuzumab Biosimilar	Zhejiang Hisun	Phase 3	Apr-18
	BC	Recombinant Humanized anti-HER2 mAb	Sunshine Guojian	NDA filed	Sep-18
	BC	TQ-B211	CTTQ	Phase 3	Oct-18
	mGC	**HLX02**	**Henlius**	**Phase 1**	**Dec-15**

Source: Company data, CMBIS

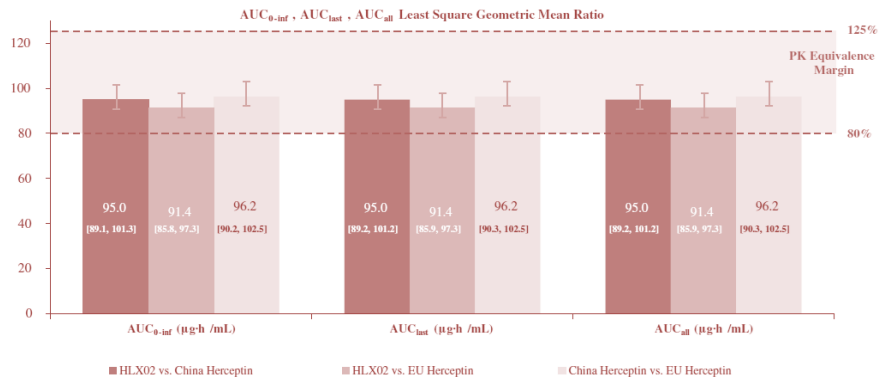
Figure 13: Summary of Herceptin biosimilars approved by FDA/ EMA

Biosimilar	Key players	Status	Approved date
Ogivri	Mylan GmbH and Biocon	NDA approved	US (Dec-17)/ EU (Dec-8)
Ontruzant	Samsung Bioepis	NDA approved	EU (Nov-17)/ US (Jan-19)
Herzuma	Celltrion and Teva	NDA approved	EU (Feb-18)/ US (Dec-18)
Kanjinti	Amgen, Breda and Allergan	NDA approved	EU (May-18)/ US (Jun-19)
Trazimera	Pfizer	NDA approved	US (Mar-19)

Source: Company data, CMBIS

Equivalent PK and comparable safety. HLX02 has completed a multi-centre, randomised, double-blind study comparing PK profiles, safety, tolerability and immunogenicity of HLX02 vs. China and EU Herceptin in 111 subjects in three cohorts. The primary endpoint is AUC 0-inf. Phase 1 trials demonstrated that HLX02 has PK bioequivalence and comparable safety results with China and EU Herceptin.

Figure 14: PK profile of HLX02 is statistically equivalent to China/ EU Herceptin



Source: Company data, CMBIS

HLX02 shows equivalence to trastuzumab in phase 3 study. HLX02 has completed a international, multi-centre Phase 3 trial. The study is a multi-centre, randomised, double-blind study to evaluate the efficacy, safety and immunogenicity between HLX02 and EU Herceptin combined with docetaxel in recurrent or previously-untreated HER2+ mBC patients. The study enrolled 649 subjects and randomised them at 1:1 ratio to two treatment arms. The primary endpoint is the ORR at Week 24. During the European Society for Medical Oncology (ESMO) Congress 2019, phase 3 study data of HLX02 was reported. ORR rates at week 24 was 71.0% for HLX02 (95% CI, 66.0%-75.9%) and 71.4% for EU Herceptin (95% CI, 66.5%-76.3%, p=0.952). The p-value at 95% CI (p=0.952) was completely contained within the pre-defined equivalence boundaries of ±13.5%. Additionally, safety and immunogenicity outcomes were similar at Week 24.

HLX03 (Adalimumab biosimilar), expect RMB1.42bn peak sales

NDA submitted and expected to receive approval by 2020E. Henlius is developing HLX03 as an adalimumab biosimilar, a TNF-α inhibitor. HLX03 started preclinical study in Jan 2012, and received IND in 4Q15 and filed NDA with NMPA in Jan 2019 for PS, RA and AS, currently under priority review by the NMPA. We expect HLX03 to be approved in early 2020E.

The global best-selling drug. Humira was originally developed by AbbVie and received US FDA approval for the treatment of RA, psoriasis (PS), juvenile idiopathic arthritis, AS, adult and paediatric Crohn's disease, ulcerative colitis, hidradenitis suppurativa and uveitis. In China, adalimumab has been approved for three indications, RA, PS and AS. Humira launched in 2002 in the US, and 2010 in China. Major patents have expired, including 2016 in the US, 2017 in China and 2018 in the European Union. According to F&S, Humira was the best-selling drug with US$20.5bn sales worldwide in 2018, while sales in China was only RMB400mn, subject to unaffordable costs and short of reimbursement coverage by NDRL. China's sales only accounted for 0.2% of global market, while China's RA, PS and AS patients accounted for ~9% of global patients, indicating significant market opportunities.

Figure 15: HLX03 sales forecasts

HLX03		2018A	2019E	2020E	2021E	2022E	2023E
RA patients in China 类风湿性关节炎	**mn**	**5.88**	**5.91**	**5.95**	**5.98**	**6.01**	**6.04**
AS patients in China 强直性脊柱炎	**mn**	**3.07**	**3.09**	**3.10**	**3.12**	**3.13**	**3.15**
PS patients in China 银屑病牛皮癣	**mn**	**6.57**	**6.60**	**6.63**	**6.67**	**6.70**	**6.73**
RA/AS/PS patients on biologics	**000**	**126**	**144**	**166**	**200**	**237**	**295**
Biologics penetration rate	*%*	*0.8%*	*0.9%*	*1.1%*	*1.3%*	*1.5%*	*1.9%*
RA/AS/PS patients on HLX03	**000**	**0**	**0**	**2**	**4**	**12**	**24**
HLX03-patient share of biologic drugs	*%*	*0%*	*0%*	*1%*	*2%*	*5%*	*8%*
Price of Humira (40mg/vial)	RMB	7593	6074	3160	3065	2973	2884
ASP of HLX03 (40mg/vial)	RMB	-	-	2,212	2,146	2081	2019
Price discount to originator	*%*	*-*	*-*	*30%*	*30%*	*30%*	*30%*
# of vial per year per patient	#	21	21	21	21	21	21
Total volume	000	-	-	35	85	253	503
Total sales (hospital-level)	RMB mn	-	-	78	183	526	1015
Total sales (ex-factory)	**RMB mn**	**-**	**-**	**69**	**161**	**464**	**896**
Humira full-course treatment cost	RMB 000	213	170	88	86	83	81
HLX03 full-course treatment cost	RMB 000	0	0	62	60	58	57

Source: F&S, PDB, CMBIS estimates

Huge untapped market. There are a large number of RA/ AS/ PS patients in China, approximately 5.87mn/ 3.07mn / 6.57mn in 2018. However, according to F&S, less than 0.2% of RA, PS and AS patients in China could afford Humira. A significant proportion of patients do not have access to Humira in the PRC due to high treatment costs and unreimbursed charges. Henlius plans to commercialise HLX03 as an affordable alternative to Humira in the PRC. We expect Henlius's HLX03 to offer a 30% price discount to Humira.

Competition landscape. FDA approved several Humira biosimilars including Amjevita developed by Amgen in Sep 2016, Cyltezo developed by Boehringer-Ingelheim in Aug 2017 and Hyrimoz developed by Sandoz in Oct 2018. Amjevita and Cyltezo have also been approved by the EMA along with Solymbic from Amgen and Imraldi from Samsung Bioepis. In China, the major competitors include Bio-Thera Solutions, Zhejiang Hisun, Innovent Biologics and Jiangsu Union Biopharma. Bio-Thera Solutions's NDA has been approved in 7 Nov, 2019. In our view, adalimumab would be a competitive market and price competition would intensify and be fierce.

Figure 16: Key competitors to Adalimumab biosimilar in late stage in China

Reference Drug	Indication	Biosimilar	Key players	Regulatory filing status as at 31/3/2019	Relevant filing/ approval date
Humira (adalimumab, AbbVie) Expiry of major patents PRC: 2017 US: 2018 EU: 2018	**PS/AS**	**HLX03**	**Henlius**	**NDA accepted**	**Jan-19**
	AS	BAT1406	Bio-Thera Solutions	NDA approved	Nov-19
	AS	HS016	Zhejiang Hisun	NDA filed	Sep-18
	AS	IBI303	Innovent Biologics	NDA filed	Nov-18
	RA	**HLX03**	**Henlius**	**Phase 1**	**Dec-16**
	RA	UBP1211	Jiangsu Union Biopharma	Phase 3	May-17

Source: Company data, CMBIS

Figure 17: Summary of Humira biosimilar approved by FDA/ EMA

Biosimilar	Key players	Status	Approved date
Amjevita	Amgen	NDA approved	US (Sep-16)/ EU (Mar-17)
Cyltezo	Boehringer-Ingelheim	NDA approved	EU (Aug-17)/ US (Nov-17)
Hyrimoz	Sandoz	NDA approved	US (Oct-18)
Imraldi	Samsung Bioepis	NDA approved	EU (Aug-17)
Hulio	Mylan and Fresenius Kabi	NDA approved	EU (Sep-18)

Source: Company data, CMBIS

Equivalent PK and comparable safety profile with reference drug. HLX03 achieved bioequivalence in PK profiles and safety and immunogenicity profiles with the reference drug in Phase 1 study, which is a single-centre, randomised, double-blind, parallel study evaluating PK, safety, tolerability, and immunogenicity of HLX03 and Humira in 220 healthy Chinese males. The primary endpoints consist of C_{max} and $AUC_{0-t.}$

Figure 18: HLX03 and Humira study groups achieved equivalent PK profile

	Geometric Mean		Geometric Ratio	90% CI
Parameters	**HLX03**	**Humira**	**HLX03/ Humira**	**HLX03/ Humira**
C_{max}(μg/mL)	3.31	3.23	102.22	96.20-108.61
AUC0-t(μg·h/mL)	1,823.32	1,724.59	105.72	97.07-115.15

Source: Company data, CMBIS

Phase 3 HLX03-PS clinical trial is a multi-centre, randomised, double-blind, positive drug parallel study comparing efficacy and safety between HLX03 and Humira in patients with plaque psoriasis. It has enrolled 216 subjects (108 subjects in each study group) at 33 sites in China. The primary endpoint consists of percentage improvement in psoriasis area severity index ("PASI") at week 16.

HLX04 (Bevacizumab biosimilar), expect RMB1.75bn peak sales

Henlius began developing HLX04 in Jan 2012 and is conducting a Phase 3 clinical trial on mCRC. We expect Henlius to file NDA of HLX04 to NMPA in 2020E for treatment of mCRC and unresectable, locally advanced, recurrent or metastatic nsNSCLC. Despite fierce competition, Henlius aims to differentiate HLX04 by being the first bevacizumab biosimilar with Phase 3 clinical data on mCRC. Furthermore, Henlius has submitted IND applications for HLX04 on wAMD and DR. Henlius is also developing HLX04 + HLX10 as one of key immuno-oncology combination therapies, which will also help increase and sustain sales for HLX04.

Global Top 7 selling drug. Avastin (bevacizumab) is a VEGF inhibitor (angiogenesis inhibitor) originally developed by Genentech. Bevacizumab has been approved by FDA for mCRC in 2004 and nsNSCLC in 2006. Avastin was launched in China in 2010. Avastin's major patents have expired, including patent expiration in 2013 in Europe, in 2016 in the US and in 2018 in China. In 2018, global sales of Avastin amounted to CHF6.8bn (~US$6.7bn) according to Roche's annual report, while sales in China was RMB3.2bn

according to F&S. Bevacizumab was added to NRDL in 2017. The incidence of mCRC and nsNSCLC is high while bevacizumab penetration rate remains low, especially in emerging markets. Due to the huge unserved patients, there are significant market opportunities for affordable Avastin biosimilars.

The most competitive biosimilar with 13 candidates in late stage in China. So far, Mvasi, an Avastin biosimilar developed by Amgen, has been approved by FDA in Sep 2017 and by EMA in Jan 2018. In China, besides HLX01, there are another twelve Avastin biosimilars in late stage. Qilu Pharm and Innovent Biologics have filed NDAs, while Genor Biopharma, Beijing mAbworks Biotechnology, Shandong Boan Biological Technology, Hengrui, TOT Biopharm etc. are conducting Phase 3 clinical trials for Avastin biosimilars on nsNSCLC. Competition of Avastin biosimilars in China market may intensify over time.

Figure 19: Key competitors to bevacizumab in late stage in China

Reference Drug	Indication	Biosimilar	Key players	Regulatory filing status as at 31/3/2019	Relevant filing/ approval date
Avastin (bevacizumab, Roche) **Expiry of major petents** **PRC: 2018** **US: 2016** **EU: 2013**	**mCRC**	**HLX04**	**Henlius**	**Phase 3**	**Mar-18**
	nsNSCLC	**HLX04**	**Henlius**	**Phase 1**	**Dec-16**
	nsNSCLC	IBI305	Innovent Biologics	NDA filed	Jan-19
	nsNSCLC	TAB008	TOT Biopharm	Phase 3	May-17
	nsNSCLC	MIL60	Beijing mAbworks Biotechnology	Phase 3	Aug-17
	nsNSCLC	BAT1706	Bio-Thera Solutions	Phase 3	Oct-17
	nsNSCLC	GB222	Genor Biopharma	Phase 3	Dec-17
	nsNSCLC	LY01008	Shandong Boan Biological Technology	Phase 3	Jan-18
	nsNSCLC	BP102	Shanghai Hengrui Pharmaceutical	Phase 3	Mar-18
	nsNSCLC	QL1101	Qilu Pharmaceutical	NDA filed	Aug-18
	nsNSCLC	TQ-B2302	CTTQ	Phase 3	Jul-18
	nsNSCLC	WBP-264	Hualan Genetic Engineering	Phase 3	Aug-18
	nsNSCLC	SCT510	Sinocelltech	Phase 3	Dec-18
	nsNSCLC	AK-3008	Anhui Anke Biotechnology	Phase 3	Apr-19

Source: Company data, CMBIS

Figure 20: Summary of Avastin biosimilar approved by FDA/ EMA

Biosimilar	Key players	Status	Approved date
Mvasi	Amgen	NDA approved	US (Sep-17)/ EU (Jan-18)

Source: Company data, CMBIS

Figure 21: HLX04-mCRC sales forecasts

HLX04-mCRC		2018A	2019E	2020E	2021E	2022E	2023E
mCRC new cases	**'000**	**424**	**437**	**450**	**462**	**475**	**489**
Stage IV%		*19%*	*19%*	*19%*	*19%*	*19%*	*18%*
Late stage patient	000	81	83	85	87	88	90
Relapsed patient pool	'000	64	65	66	67	68	69
Total addressable mCRC new Cases in China	**000**	**145**	**148**	**151**	**154**	**156**	**160**
Eligible mCRC patient pool	**'000**	**81**	**85**	**89**	**93**	**97**	**102**
% Digosis rate		*70%*	*71%*	*72%*	*73%*	*74%*	*75%*
% mCRC treatment rate		*80%*	*81%*	*82%*	*83%*	*84%*	*86%*
Total mCRC patients on bevacizumab	**000**	**13**	**16**	**20**	**23**	**27**	**31**
Penetration rate		*16%*	*19%*	*22%*	*25%*	*28%*	*30%*
mCRC patients on HLX04	**'000**	**0**	**0**	**0**	**2**	**5**	**9**
HLX04-patient share		*0%*	*0%*	*0%*	*10%*	*20%*	*30%*
Price of Avastin, 100mg/vial	RMB	1,998	1,934	1,876	1,820	1,765	1,712
Price of HLX04, 100mg/vial	RMB	-	-	-	1,274	1,236	1,199
Price discount to originator		-	-	*0%*	*30%*	*30%*	*30%*
# of vials per year per patient	#	37	39	39	39	39	39
Total volume	000	-	-	-	91	213	358
Total sales (hospital-level)	RMB mn	-	-	-	116	263	430
HLX04-mCRC sales (ex-factory)	**RMB mn**	**-**	**-**	**-**	**102**	**232**	**379**
Avastin full-course treatment cost	RMB 000	112	109	106	102	99	96
HLX04 full-course treatment cost	RMB 000	-	-	-	72	70	67

Source: F&S, PDB, Chinese Protocol of Diagnosis and Treatment of Colorectal Cancer (2015 edition), CMBIS estimates

Figure 22: HLX04-NSCLC sales forecasts

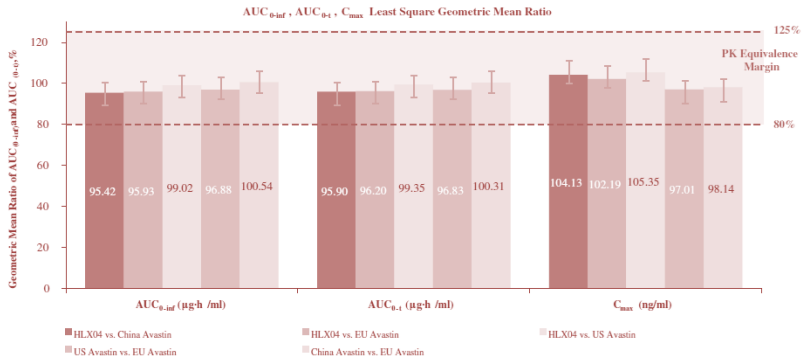
HLX04-NSCLC		2018A	2019E	2020E	2021E	2022E	2023E
NSCLC new cases	**'000**	**737**	**778**	**798**	**818**	**839**	**862**
StageIIIb+IIIC+IV	000	571	600	613	625	637	650
Relapsed patient pool	'000	205	216	222	228	234	240
Total NSCLC new cases in China	000	777	817	835	852	870	890
% Non-squamous NSCLC new cases	*%*	*75%*	*75%*	*75%*	*75%*	*75%*	*75%*
Non-squamous NSCLC new cases	'000	583	613	626	639	653	668
% EGFR testing rate	*%*	*92%*	*92%*	*93%*	*93%*	*93%*	*93%*
% EGFR wild type	*%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*
Total NSCLC addressable cases in China (EGRF wildtype)	**000**	**187**	**197**	**203**	**207**	**211**	**216**
Total NSCLC patients on bevacizumab	'000	11	17	23	29	35	42
Penetration rate	*%*	*6.4%*	*9.4%*	*12.4%*	*15.4%*	*18.4%*	*21.4%*
NSCLC patients on HLX04	000	0.00	0.00	0.00	1.44	3.51	8.34
HLX04 patient share	*%*	*0%*	*0%*	*0%*	*5%*	*10%*	*20%*
Price of Avastin	RMB	1,998	1,934	1,876	1,820	1,765	1,712
Price of HLX04, 100mg/vial	RMB	-	-	-	1,274	1,236	1,199
Price discount to originator	*%*	*0%*	*0%*	*0%*	*30%*	*30%*	*30%*
# of vials per year per patient	#	89	91	94	94	94	94
Total volume	000	-	-	-	135	328	781
Total sales (hospital-level)	RMB mn	-	-	-	171	406	936
HLX04-NSCLC sales (ex-factory)	**RMB mn**	**-**	**-**	**-**	**151**	**358**	**826**
Avastin full-course treatment cost	RMB 000	234	226	219	213	207	200
HLX04 full-course treatment cost	RMB 000	-	-	-	149	145	140

Source: F&S, PDB, CMBIS estimates

PK bioequivalence. Phase 1 clinical trial of HLX04 was a multi-centre, randomised, double-blind, four-arm parallel study comparing the PK, safety and immunogenicity of HLX04, Avastin sold in the US ("US Avastin"), Avastin sold in the EU ("EU Avastin") and Avastin sold in the PRC ("China Avastin"). The study enrolled 208 subjects. The primary endpoints consisted of AUC0-inf and AUC0-t. Phase 1 clinical trial demonstrated four-way PK bioequivalence among HLX04 and all three differently sourced Avastin.

To differentiate HLX04 by being the first biosimilar with Phase 3 clinical data on mCRC. The Phase 3 HLX04-mCRC clinical trial is a multi-centre, randomised, double-blind, parallel study comparing efficacy, safety and immunogenicity between HLX04 and Avastin combined with chemotherapy regimens as the first line treatment in patients with mCRC. The study plans to enrol ~638 subjects in China. The primary endpoint consists of the PFS rate at week 36 ("$PFSR_{36w}$"). Henlius expects to complete the trial in 2019 and submit NDA in 2020.

Figure 23: PK profile of HLX04 is equivalent to China/ US/ EU Avastin



Source: Company data, CMBIS

Furthermore, in addition to above four biosimilars, Henlius has another six biosimilars at early stage, covering hot drug targets, such as EGFR, VEGFR2, HER2, CTLA-4 and CD-38.

Figure 24: Other biosimilars at early stage

Product (Reference Drug)	Target	Indication	Commercial Rights	Status
HLX05 (Erbitux, Merck)	EGFR	mCRC/SCCHN	Worldwide (ex-China)	Phase 1
HLX12 (Cyramza, Eli Lilly)	VEGFR2	Gastric cancer, NSCLC, mCRC	Worldwide	Phase 1
HLX11 (Perjeta, Roche)	HER2	BC	Worldwide	IND
HLX14 (Xgeva, Amgen)	RANK ligand	Solid tumours	Worldwide	Pre-clinical
HLX13 (Yervoy, BMS)	CTLA-4	Solid tumours	Worldwide	Pre-clinical
HLX15 (Darzalex, Johnson&Johnson)	CD-38	Multiple Myeloma	Worldwide	Pre-clinical

Source: Company data, CMBIS

Robust pipeline in novel mAbs and combo therapies

According to F&S, China's biologics will grow at 19.6% CAGR in 2018-23E, rising from RMB262.2bn in 2018 to RMB641.2bn in 2023E. China's mAbs sales only accounted for 6.1% of overall biologics market in 2018, vs. 55.3% of global market, representing a sizable market potential. China mAbs market is expected to grow at 57.9% CAGR in 2018-23E, from RMB16bn in 2018 to RMB156.5bn in 2023E, driven by new treatments and rapid growth of mAb biosimilars.

Henlius has a diversified portfolio of innovative mAbs in Phase 1b/2 clinical studies, including HLX06 (a novel VEGFR2 inhibitor), HLX07 (an EGFR inhibitor), HLX10 (a novel PD-1 inhibitor), HLX20 (a novel PD-L1 inhibitor) and HLX22 (a HER2 inhibitor). Besides, its combination therapy (HLX04 + HLX10) has entered into Phase 3 clinical trials, being the first combo trial on bevacizumab and PD-1 inhibitor in China. Another combination therapy (HLX07 + HLX10) has filed IND. Henlius will explore more combo therapies using its biosimilars or innovative drugs with PD-1 or PD-L1, as key strategy to sustain growth.

Figure 25: Innovative biologic drugs in clinical trials

Product	Target	Indication	Commercial Rights	Status
HLX01	CD20	RA	Worldwide	Phase 3
HLX04	VEGF	wAMD/DR	Worldwide	IND approved
HLX07	EGFR	Solid tumours	Worldwide	Phase 2
HLX06	VEGFR2	Solid tumours	Worldwide	Phase 1
HLX10	PD-1	Solid tumours	Worldwide	Phase 2
HLX20	PD-L1	Solid tumours	Worldwide	Phase 1
HLX22	HER2	Solid tumours	Worldwide	Phase 1
HLX55	cMET	Solid tumours	Asia	IND approved
HLX04 + HLX10	VEGF + PD-1	Solid tumours	Worldwide	Phase 3
HLX07 + HLX10	EGFR + PD-1	Solid tumours	Worldwide	IND filed
HLX10 + Chemo	PD-1	Solid tumours	Worldwide	Phase 3

Source: Company data, CMBIS

HLX01 (RA), expect RMB784mn peak sales

Henlius is developing HLX01 for a new indication of RA in China, which is not yet approved indication for the originator. The Company targets to file NDA for HLX01-RA in 2020E.

HLX01 requires cheaper costs than TNF inhibitors and less frequency of administration. HLX01 only needs to be injected once weekly for two weeks, repeated every 6-9 months, while other biologics RA drugs require injections every 2-4 weeks with higher treatment cost. As per our estimates, the full-course treatment cost of HLX01-RA might be cheaper than TNF inhibitor, at around RMB48,000, vs. ~RMB75,000 for Yisaipu and RMB70,000-140,000 for Humira.

Phase 3 study is ungoing. The Phase 3 study focuses on the efficacy and safety of HLX01 compared to placebo, administered together with methotrexate, in RA patients who had shown an incomplete response to treatment with methotrexate alone. The study plans to enrol 267 subjects. The primary endpoint is at least ACR20 (meaning at least a 20% improvement in RA symptoms) at week 24. Phase 3 study is still ongoing and efficacy and safety findings were not yet available.

Figure 26: HLX01-RA sales forecasts

HLX01-RA		2018A	2019E	2020E	2021E	2022E	2023E
Total RA patients in China	**mn**	**5.88**	**5.91**	**5.95**	**5.98**	**6.01**	**6.04**
% Diagnosis rate of patients	*%*	*0.42%*	*0.42%*	*0.42%*	*0.42%*	*0.42%*	*0.42%*
% Moderate to severe patients	*%*	1.97	2.05	2.13	2.21	2.30	2.38
% drug treated patients	*%*	*71%*	*71%*	*71%*	*71%*	*71%*	*71%*
% of advanced treatment eligible patients	*%*	*65%*	*66%*	*68%*	*69%*	*70%*	*71%*
Advanced treatment eligible patients	000	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*
# of patients eligible for 1L biologics	**000**	450	476	503	531	561	593
# of patients on 2/3L biologics	**000**	**51**	**57**	**70**	**85**	**101**	**119**
Penetration rate	*%*	*11%*	*12%*	*14%*	*16%*	*18%*	*20%*
Patients on HLX01-RA	**000**	**0.00**	**0.00**	**0.00**	**1.49**	**2.48**	**3.73**
HLX01-RA patient share	*%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*
Price of MabThera	RMB	2418	2297	1953	1913	1875	1838
ASP of HLX01, 100mg/vial	RMB	0	1398	1367	1339	1313	1286
Price discount to originator	*%*	-	*39%*	*30%*	*30%*	*30%*	*30%*
# of vial per year per patient	vial	21	22	22	23	24	24
Total volume	000	-	-	-	34	58	90
Total sales (hospital-level)	RMB mn	-	-	-	54	88	130
Total sales (ex-factory)	**RMB mn**	**-**	**-**	**-**	**47**	**77**	**114**
MebThera standard treatment cost	RMB 000	73	69	59	57	56	55
HLX01 standard treatment cost	RMB 000	**-**	42	41	40	39	39

Source: F&S, PDB, CMBIS estimates

HLX07 (Cetuximab biobetter), expect RMB468mn peak sales

HLX07 is a recombinant humanised anti-epidermal growth factor receptor ("EGFR") monoclonal antibody, as a cetuximab biobetter. Cetuximab initially received FDA approval for the treatment of mCRC with wild-type KRAS in 2004 and SCCHN in 2006. In China, cetuximab was approved by NMPA for mCRC with wild-type KRAS and EGFR overexpression in 2006. Screening for overexpressed EGFR or KRAS mutation is typically conducted before treatment in order to rule out patients who are unlikely to respond to cetuximab.

In 2018, cetuximab was included in the NRDL in China with price of RMB1,295 per 100 mg vial. The incidence rates of mCRC and SCCHN is high in China. 2018 global sales of cetuximab amounted to US$1.5bn, while sales in China was around RMB0.5bn.

No biosimilar approved yet worldwide. A number of cetuximab biosimilars are under development globally, none of which have yet been approved. In China, Kelun and Sinomabtech are conducting Phase 3 clinical trials on cetuximab biosimilars. In addition, other anti-EGFR mAb which are available in certain markets, but are generally not as widely distributed as cetuximab, include panitumumab (brand name Vectibix) from Amgen, which received FDA approval in 2006 for EGFR-expressing mCRC, and nimotuzumab developed by the Centre of Molecular Immunology, approved for glioma in the US and EU as well as for SCCHN in China, India and certain other countries.

Biobetter with superior safety. Henlius began developing HLX07 in Jan 2014. As a biobetter, HLX07 may be superior to cetuximab in terms of safety since HLX07 is a humanised monoclonal antibody rather than a chimeric human-murine antibody. Potential advantages of HLX07 were also found in pre-clinical studies. Currently, it is conducting Phase 1b/2 clinical trials in China and Phase 1a clinical trial in Taiwan. Phase 1b/2 HLX07 clinical trial is an open-label, Bayesian optimal interval ("BOIN") design adaptive dose-escalation study exploring the safety, tolerability, PK and efficacy when administering HLX07 in combination with different chemotherapy regimens with endpoints of the incidence of DLT and MTD. Phase 1a/b remains ongoing, and thus efficacy and safety were not yet available. Henlius plans to launch HLX07 initially in China, where there is a significant underserved treatment need due to high cost.

HLX10 (PD-1 inhibitor), expect RMB3.25bn peak sales including combo therapies

Henlius is developing HLX10, as a recombinant humanised monoclonal antibody against PD-1 for treating various solid and haematological tumours. It started developing HLX10 in early 2014 and obtained IND approvals in the US, Taiwan and Mainland China in Sep 2017, Dec 2017 and Mar 2018, respectively. HLX10 monotherapy was undergoing phase 1a clinical trial in Taiwan and the US and phase 2 trial in Mainland China.

On 30 Sep, 2019, Henlius and PT Kalbe Genexine Biologics (KG Bio) entered into an Exclusive License Agreement for HLX10, where KG Bio will be granted exclusive rights to develop and commercialize HLX10 in relation to monotherapy for solid tumour (MSI-high) and two combination therapies in ten countries in Southeast Aisa at the consideration of 1) non-creditable payment of US$10mn, 2) commercial sales milestone payments not exceeding US$650mn, 3) regulatory milestone payments not exceeding US$22mn, and 4) US$10mn to fund the two combination therapy trials.

Broad-spectrum drugs with large patient population. PD-1/PD-L1 inhibitors are broad-spectrum novel drugs and they have become common therapies for a variety of malignancies, including melanoma, NSCLC, head and neck cancer, bladder cancer and renal cancer, etc. A significant and growing market has developed as a result due to the broad indications. According to F&S, 2018 global sales of Opdivo and Keytruda reached US$7.6bn and US$7.2bn, respectively.

Despite of intense competition, HLX10 leads in combo therapies. A number of PD-1 or PD-L1 antibody drugs have been approved by the FDA. These include Merck's Keytruda (pembrolizumab), Bristol-Myers Squibb's Opdivo (nivolumab), Roche's Tecentriq (atezolizumab), AstraZeneca's Imfinzi (durvalumab), Pfizer's Bavencio (avelumab) and Regeneron's Libtayo (cemiplimab). Several PD-1 or PD-L1 antibody agents are in clinical development, such as Novartis' PDR-001, Tesaro's TSR042 and Pfizer's PF-06801591. In China, imported Opdivo (nivolumab) and Keytruda (pembrolizumab), and domestic PD-1 inhibitors from Junshi Biosciences, Innovent Biologics and Hengrui were approved, while BeiGene has filed NDA with the NMPA, pending for approval. Despite fierce competition and being a late entrant, Henlius aims to compete on combination therapy, which may deliver better efficacy than monotherapy.

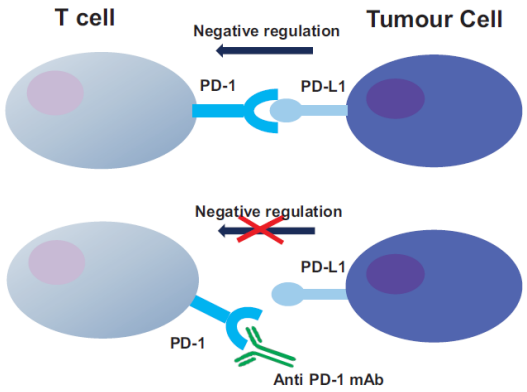
Figure 27: Summary of PD-1 inhibitors launched and in late stage in China

Drug	Player	Indication	IND time	NDA submission time	Regulatory filing/ approval status	Approved date	Price
Opidivo (nivolumab)	BMS	Locally advanced or metastatic NSCLC	Jul-15	Nov-17	Approved	Jun-18	RMB 9,260/100mg
Keytruda (pebrolizumab)	Merck	Locally advanced or metastatic melanoma	Feb-16	Feb-17	Approved	Jul-18	RMB 17,918/100mg
Tuoyi (Toripalimab)	Junshi Biosciences	Second-line treatment for melanoma	Dec-15	Mar-18	Approved	Dec-18	RMB 7,200/240mg
Daboshu (Sintilimab)	Innovent Biologics	r/r CHL	Sep-16	Apr-18	Approved	Dec-18	RMB 7,838/100mg
SHR-1210 (Camrelizumab)	Hengrui	Classical Hodgkin's Lymphoma	Feb-16	Apr-18	Approved	May-19	RMB 19,800/ 200mg
BGB-A317	BeiGene	Classcical Hodgkin's Lymphoma	Sep-16	Aug-18	Under review	N/A	N/A

Source: F&Ss, NMPA, CMBIS

PD-1 mechanism of action. PD-1 is an immune checkpoint inhibitor located on the surface of T-cells. Its normal function is to turn off T-cell mediated immune response or stop the immune system from attacking other cells in the body. This process works when PD-1 binds to PD-1 ligand 1 (PD-L1) or PD-1 ligand 2 (PD-L2) on the surface of normal cell or cancer cell. Many cancer cells develop overexpression of PD-1 and PD-2, which help to evade T-cell attacks. PD-1 inhibitors can bind to PD-1 receptor and block the interaction between PD-L1 and PD-1 receptor, which allows the T-cells to kill cancer cells.

Figure 28: Mechanism of PD-1 inhibitor



Source: Company data, CMBIS

HLX10 showed good binding ability to PD-1 receptor in pre-clinical studies. In pre-clinical studies, in vitro studies demonstrated HLX10's ability to bind to the PD-1 receptor of activated T-cells and block PD-L1/PD-L2 from triggering immunosuppression. In vivo studies, HLX10 demonstrated significant ability to inhibit PD-L1 receptors on human colorectal cancer and NSCLC tumour cells on xenografted mice, along with favourable safety observations.

Phase 1a showed HLX01 well tolerated by patients. Phase 1a clinical trial is an open-label, BOIN adaptive dose-escalation study to identify safety and the maximum tolerated dose ("MTD") of HLX10 in patients with metastatic or recurrent solid tumours. Primary endpoints include MTD and percentage of patients with AEs. During CSCO 2019, results of phase 1 study were released. As of 31 Jul, 2019, HLX10 monotherapy have 17 patients enrolled. Of 13 evaluable subjects, six patients achieved stable diseases and one patient experienced PD.
Phase 1 trial showed that HLX10 monotherapy was well tolerated in patients with advanced solid tumors and showed promising anti-tumor activity and comparable PK to those of nivolumab and pebrolizumab.

HLX04 + HLX10 (bevacizumab + PD-1)

Although immune checkpoint inhibitors have successfully achieved sustained responses in many different types of malignant diseases, they are only effective in a fraction of patients in each type of tumours and have limitation to subsets of patients with response rates of 20% or less. Accordingly, a variety of immuno-oncology combination therapies have been developed or are under development, which in turn enables immune checkpoint inhibitors to not be limited to specific tumour types and be more likely to effectively treat malignant diseases with specific immunobiologic characteristics.

HLX10 has demonstrated high efficacy when administered together with chemotherapy, radiation therapy or other mAb drug candidates, including HLX04 and HLX07. Henlius plans to explore using PD-1/ PD-L1 inhibitors as backbone in combination with chemotherapy, radiotherapy, targeted therapies, vaccines or small molecules for various

indications. Henlius has commenced phase 3 trial of HLX04 + HLX10 combination therapy, which is the domestic first approved combo IND using PD-1 and bevacizumab.

Phase 1/2 clinical trial underway and prepared for Phase 3. HLX04 + HLX10 combination therapy is in Phase 3 clinical trial for nsNSCLC and Phase 2 clinical trial for HCC, respectively.

Phase 3 clinical trial for nsNSCLC will consist of two parts. Part I is a safety run in an open-label, single-arm, non-randomised study evaluating primarily the safety and tolerability of the combo therapy. Part II is designed as a three-arm, randomized, double-blind, multi-center clinical trial, evaluating safety and efficacy. The study plans to enrol 636 to 642 subjects, with 6-12 for Part I and 630 for Part II. The primary endpoints for Part I will consist of safety and tolerance, and for Part II will consist of PFS.

Phase 2 clinical trial for HCC plans to enrol 150 subjects and the study is designed as a multi-stage, single-arm, randomised, open-label clinical trial, evaluating safety and efficacy of the combo with primary endpoints of ORR, AE and SAE, etc.

Figure 29: Overview of Henlius's PD-1 combination therapies

Product	Target	Indication	Commercial Rights	Status
HLX04 + HLX10	VEGF + PD-1	nsNSCLC	Worldwide	Phase 3
HLX04 + HLX10	VEGF + PD-1	HCC	Worldwide	Phase 2
HLX07 + HLX10	EGFR + PD-1	SCCHN	Worldwide	IND filed
HLX10 + Chemo	PD-1	mESCC	Worldwide	Phase 3
		sqNSCLC	Worldwide	Phase 3
		SCLC	Worldwide	Phase 3
		GC	Worldwide	Phase 3

Source: Company data, CMBIS

In November 2019, Henlius has entered into cooperation with Ascentage Pharma (6855 HK) to co-develop the combination therapy of HLX01 and APG-2575, a novel Bcl-2 selective inhibitor, for the treatment of chronic lymphocytic leukemia (CLL) in China.

Henlius has rich innovative drug candidates at early stage, including drug targets of CTLA-4, CD47, TIGIT, etc.

Figure 30: Other bio-innovative drug candidates at early stage

Product	Target	Indication	Commercial Rights	Status
HLX56	DR	Solid tumours	The great China	Pre-clinical
HLX09	CTLA-4	Solid tumours	Worldwide	Pre-clinical
HLX23	CD73	Solid tumours	Worldwide	Pre-clinical
HLX24	CD47	Solid tumours	Worldwide	Pre-clinical
HLX26	LAG3	Solid tumours	Worldwide	Pre-clinical
HLX59	CD27	Solid tumours	Worldwide	Pre-clinical
HLX51	OX40	Solid tumours	Worldwide	Pre-clinical
HLX52	TIM-3	Solid tumours	Worldwide	Pre-clinical
HLX53	TIGIT	Solid tumours	Worldwide	Pre-clinical
HLX58	Claudin 18.2	Solid tumours	Worldwide	Pre-clinical
HLX63	GPC3	Solid tumours	Worldwide	Pre-clinical

Source: Company data, CMBIS

Commercial-scale manufacturing capabilities with significant cost efficiencies

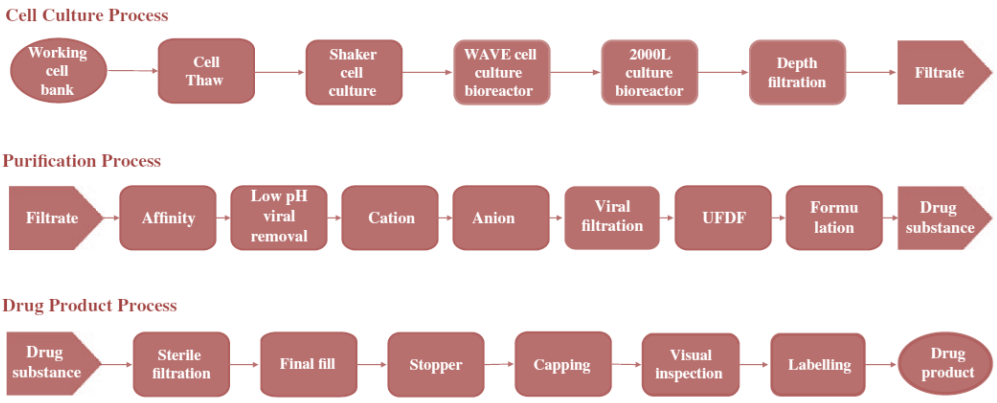
Biologics have more complex molecular structure than chemical drugs. They are derived from living organisms, thus influenced by specifics of the manufacturing process. Henlius has its own manufacturing facility, complied with China GMP and international cGMP standards.

Henlius has its own manufacturing facility for mAb products in Xuhui, Shanghai. It is located in Shanghai Caohejing Hi-Technology Park with area of ~11,000 square metres. It has six 2,000L single-use bioreactors and four 500L single-use bioreactors, amounting to total capacity of 14,000L, which was one of the largest capacities among domestic biopharmaceutical companies. A new manufacturing facility in Songjiang, Shanghai is under construction which will further strengthen the Company's commercial capability.

Henlius utilises single-use technologies in the production process, such as disposable bioreactors and filtration systems. Compared to traditional stainless steel bioreactors, single-use bioreactors have many advantages, 1) improving operation efficiency, such as shorter downtimes, reduced cleaning and sterilisation efforts, lower risk of cross contaminations, flexibility and easy shifts in portfolios based on market needs, 2) saving in capital investment and production cost. According to F&S, single-use bioreactors generally reduce capital expenditure by up to 50% and production costs by up to 25% to 30%, and save the need for clean-up and disinfection after each cycle, which reduces per-batch production time and decreases the risk of contamination.

As of 31 Mar 2019, Henlius had 155 personnel engaged in manufacturing, 42 of whom were responsible for pilot production for IND filings and Phase 1 and Phase 2 clinical trials, while 98 personnel were responsible for Phase 3 clinical and eventual commercial production.

Figure 31: Overall manufacturing process



Source: Company data, CMBIS

Leveraging global partners on commercialization and R&D

Henlius aims to provide high-quality, affordable and innovative drugs to patients globally. It will sell products through in-house marketing teams and collaboration with partners.

In China, Henlius will sell products through in-house marketing team and also leverage the strong sales expertise of Fosun Pharma, its parent company. Henlius has entered into commercial cooperation with Fosun Pharma and Jiangsu Wanbang with regard to the products of HLX01 and HLX03 respectively. In our view, Henlius will benefit from the collaboration, given that Fosun Pharma's 1) superior market access ability, 2) extensive sales network covering higher and lower tier markets. In addition, Henlius plans to establish its sales team, focusing on the field of oncology.

For overseas market, it has partnered with global pharmaceutical companies, such as Biosidus, Accord, Cipla, Jacobson, KG Bio, etc. Henlius authorized overseas commercialisation rights of HLX01 to Biosidus, and HLX02 to Accord, Cipa and Jacobson Medical in different jurisdictions, enabling it to leverage its global partners' competitive edge in commercial experience and mature sales channels. In September 2019, Henlius licensed out commercial rights of HLX10 in South East Asia regions to KG Bio for a total milestone payment of up to US$692mn. In November 2019, Henlius has entered into cooperation with Ascentage Pharma (6855 HK) to co-develop the combination therapy of HLX01 and APG-2575, a novel Bcl-2 selective inhibitor, for the treatment of chronic lymphocytic leukemia (CLL) in China.

Figure 32: Global collaboration partners

Deal	Drug	Region	Partner	Right	Payments	Follow-up arr.
Cooperation	HLX01	The PRC	Fosun Pharma	Fosun Pharma owns exclusive commercial right in the PRC	Fosun Pharma will fully reimburse Phase 3 study cost	Henlius and Fosun Pharma will equally share net profit from all sales of HLX01 in the PRC.
		South American	Biosidus			
		China	Ascentage	Strategic collaboration with Ascentage Pharma, working together to conduct clinical trials of the combination therapy between HLX01 and APG-2575, a novel Bcl-2 selective inhibitor developed by Ascentage Pharma, for the treatment of CLL in China.		
	HLX02	Europe, MENA and CIS	Accord	Exclusive commercial right for HLX02 in over 70 jurisdictions and regions in Europe, MENA and CIS	US$8mn Upfront payment, milestone payment upon the occurrence of certain events	Henlius is entitled to commercial sales milestone payments and share profit with Accord.
		Hong Kong, Macau	Jacobson Medical	Exclusive commercial right to promote and distribute HLX02 in Hong Kong and Macau.	Jacobson Medical will make non-refundable good faith payments in three instalments	
		Australia, New Zealand, Colombia and Malaysia	Cipla	Exclusive licensing and commercialization rights in Australia, New Zealand, Colombia and Malaysia, including regulatory approval for HLX02 in those jurisdictions	Cipla is responsible for obtaining regulatory approvals and shall bear any further R&D cost required by local regulators.	Henlius will manufacture HLX02 and supply to Cipla
	HLX03	The PRC	Jiangsu Wanbang	Jiangsu Wanbang has the exclusive right to promote and commercialise HLX03 in the PRC	Jiangsu Wanbang will reimburse all clinical trial cost incurred for HLX03.	Henlius and Jiangsu Wanbang will equally share the net profit from all sales in the PRC.
	HLX10	Southeast Asia	KG Bio	Henlius granded KG Bio exclusive rights to develop and commercialize HLX10 in monotherapy and two combination therapies in Southeast Asia.		
License out	HLX05	The PRC	Shanghai Jingze	Exclusive right to develop and commercialise our drug candidate HLX05 in China	Staged payments in accordance with the milestones	Henlius will provide technical support and assistance to Shanghai Jingze in production.
License in	HLX56	Greater China	Galaxy Biotech	Henlius was granted an exclusive license to develop and commercialise its monoclonal antibody D114, HLX56.	Staged payments + one-off payments + royalty payments	
	HLX22	Greater China	AbClon	Henlius was granted an exclusive license to develop and commercialise its proprietary antibody AC101, HLX22 in Greater China.	Two instalment payments + milestone payments + royalty payments	
	HLX55	Greater China and certain countries in Southeast, Central and South Asia	Kolltan	Henlius was granted exclusive license to develop and commercialize IgG2 monoclonal antibody KTN0216, HLX55.	An upfront payment and further payments	

Source: Company data (As of Dec 31 2018, Fosun Pharma held~61% stake in Henlius, and Jiangsu Wanbang is a wholly-owned subsidiary of Fosun Pharma), CMBIS

Visionary co-founders and leadership team

The co-founders, Dr. LIU and Dr. JIANG, are seasoned scientists in the biopharmaceutical industry. Dr. LIU has~ 25 years of experience in biopharmaceutical R&D, manufacturing and quality management, and business development. He held senior positions in a number of leading multinational pharmaceutical companies, including director of the quality analytical labs at Amgen, associate director of biologics quality control at Bristol-Myers Squibb and vice president of R&D in Asia at United Biomedical.

Dr. JIANG has ~25-year experience in biopharmaceutical development and production with specialised expertise in antibody and protein engineering. He held senior researcher and director positions in several well-known global pharmaceutical companies, including VasGene Therapeutics and Applied Molecular Evolution, an affiliate of Eli Lilly.

Besides Henlius has assembled a team of highly-skilled talents, comprised by 79 industry experts, nearly 67% of whom have more than 10-year industry experience, and more than 62% have worked overseas, with experience across drug development, CMC, plant design, pharmaceutical production management, quality and compliance, clinical development, regulatory affairs, commercialisation and finance at leading multinational pharmaceutical companies.

Figure 33: Visionary leadership team with rich industry experience

Name	Age	Position	Join time	Roles	Experience	Education
Dr. Scott Shi-Kau Liu	56	Executive Director, CEO and Chairman	Feb-10	Company strategic and overall management	Deputy professor, National Sun Yat-sen University of Taiwan (1993-1994); Director for quality and regulaory affairs in United Biomedical, Inc., (1998-2003); Associate director in biologics quality control at BMS (2003-2007); Director of quality analytical labs at Amgen (2007-2008)	Ph.D. degree in biology from Purdue University; Postdoctoral training in biology at Stanford University (1991-1993)
Dr. Wei-Dong Jiang	56	Co-founder, Chief Science Officer	Feb-10	R&D	Senior researcher at Applied Molecular Evolution Inc. (2000-2004); Director for R&D at Vasgene Therapeutics Inc. (2006-2007)	Ph.D. degree in natural sciences from Giessen University; Postdoctoral training in biology at the University of California (1990-1993)
Mr. Xinjun Guo	47	Vice President and Secretary of the Board	Feb-10	Secretary work for the Board and public relationship management	Secretary of the board and deputy general manager of Zhejiang Cifu Pharmaceutical Co., Ltd. (2004-2009); Chief engineer at Shanghai Clone High Technology Co., Ltd in 2009	Master degree of business administration from Zhejiang University in 2005
Mr. Zidong Zhang	38	Chief Financial Officer	Mar-18	Financial operation, financing and investment activities	Equity analyst for UBS in New York (Sep 2014-Mar 2018); Internal consultant for Bayer AG (2011-2014)	Bachelor degree in chemistry from Fudan University; Ph.D in biochemistry from Boston University;

Source: Company data, CMBIS

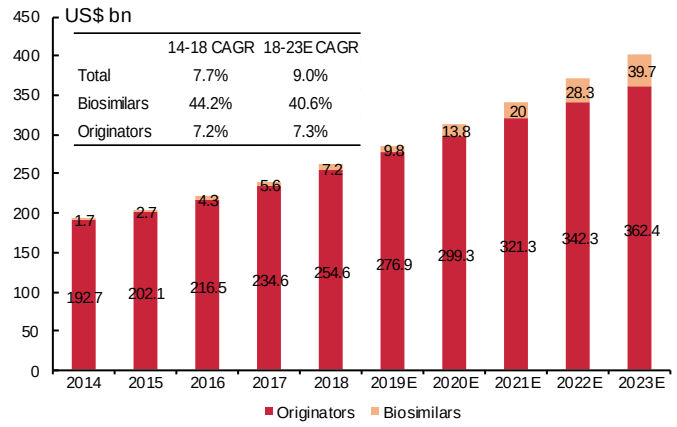
Industry Overview and Market Opportunities

The global biologics market overview

Global biologics market: A US$261.8bn market with 9% CAGR in 2018-23E

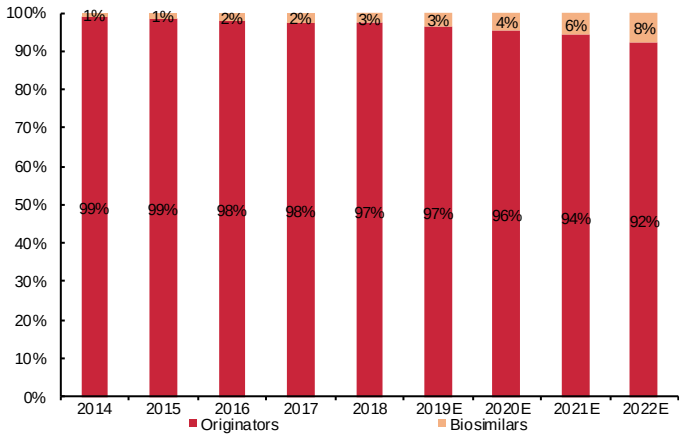
Global biologics market is booming. According to F&S, of the global top-10 selling drugs, nine were biologics. As per F&S, the global biologic market grew at 7.7% CAGR from US$194.4bn in 2013 to US$261.8bn in 2018 and is expected to grow at 9% CAGR in 2018-23E, driven by 1) superior efficacy of biologics, 2) significant development in biotechnology, 3) increasing investment in biologics R&D, and 4) growing biosimilar market.

Figure 34: Global biologics market will grow at 9% CAGR



Source: F&S, CMBIS

Figure 35: Global biologics market breakdown by originator and biosimilar

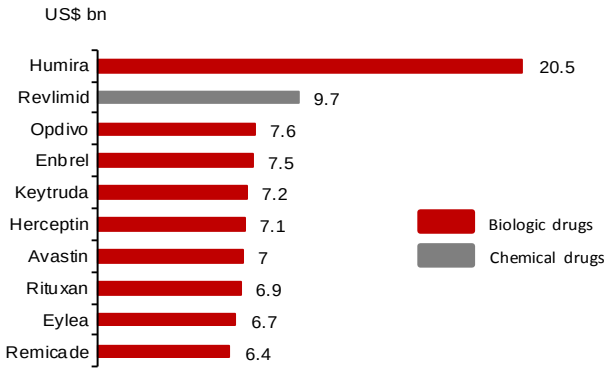


Source: F&S, CMBIS

MAbs are the largest segment constituted 55.3% of global biologics market in 2018

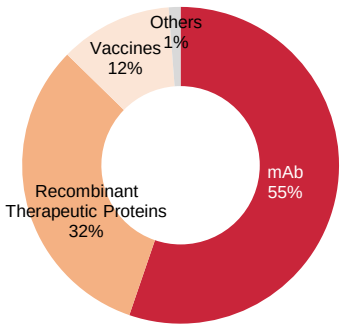
Biologics are classified into four segments, 1) mAbs, 2) recombinant therapeutic proteins, 3) vaccines, and 4) blood and blood component, allergenics, somatic cells, gene therapy and tissues, etc. According to F&S, mAbs made up 55.3% of global biologics sales in 2018, followed by 32% of recombinant therapeutic proteins. The global mAbs (including fusion proteins) was US$144.8bn in 2018. Oncology and auto-immune diseases are the two largest therapeutic areas of mAbs, accounting for~48.7% and 34.5% of mAbs market.

Figure 36: Of the global top-10 selling drugs in 2018, nine were biologics



Source: F&S, CMBIS

Figure 37: The mAb occupied the global biologics market with 55.3% market share in 2018



Source: F&S, CMBIS

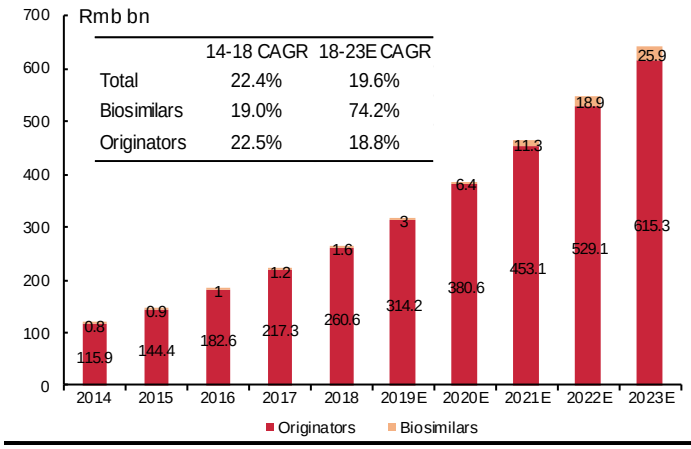
China's biologics market overview

China biologics market: a RMB262.2bn market with 19.6% CAGR in 2018-23E

According to F&S, China's biologics market grew dramatically from RMB116.7bn in 2014 to RMB262.2bn in 2018, driven by a growing increasing affordability, healthcare awareness and favourable government policies. China biologics market is expected to grow at 19.6% CAGR in 2018-23E to RMB641.2bn, driven by 1) growing disease incidence, 2) increasing capital investment, 3) regulatory reform and favourable government policies, 4) increasing affordability and healthcare awareness, and 5) establishment of a Biosimilar Pathway.

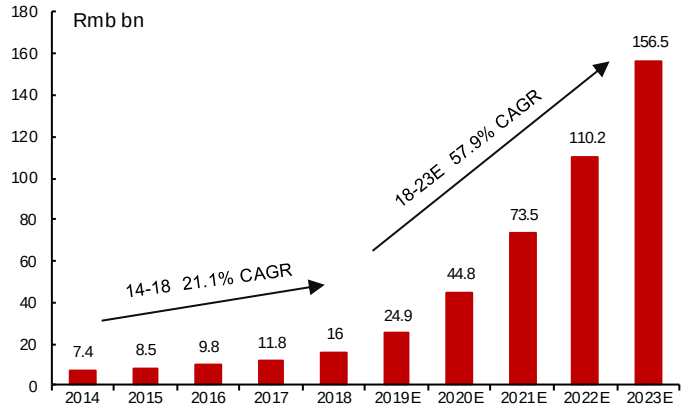
Underdeveloped mAbs market with low penetration. China's mAbs sales only accounted for 6.1% of overall biologics market in 2018, vs. 55.3% of global market, representing a sizable market potential. According to F&S, China mAbs market is expected to grow at 57.9% CAGR in 2018-23E, from RMB16bn in 2018 to RMB156.5bn in 2023E (~24.4% of biologics market).

Figure 38: China biologics market forecast by drug type



Source: F&S, CMBIS

Figure 39: China mAbs market to grow at 57.9% CAGR

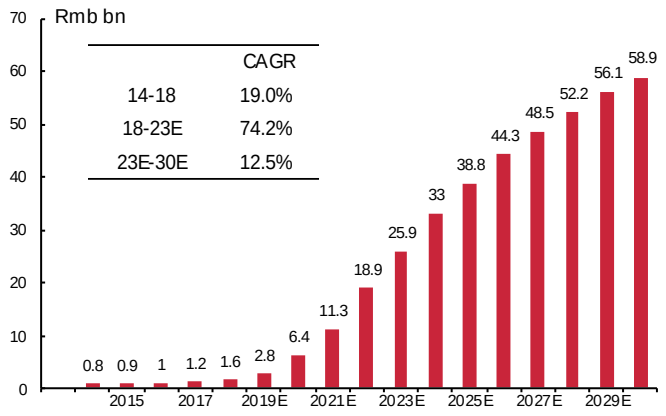


Source: F&S, CMBIS

China Biosimilars market driven by supply and medical reimbursement

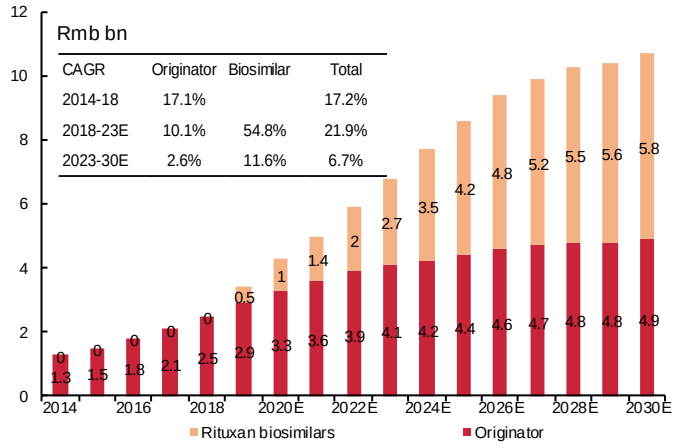
According to F&S, China's biosimilars market is expected to grow at 74.2% CAGR in 2018-23E, from RMB1.6bn in 2018 to RMB25.9bn in 2023E, driven by 1) the establishment of biosimilars guidelines, 2) the inclusions of biological drugs into the NRDL and potential more inclusions through price negotiations, and 3) near-term and medium-term patent expiration of a larger number of "blockbuster" biologics.

Figure 40: China biosimilars market to blossom



Source: F&S, CMBIS

Figure 41: China rituximab market forecast



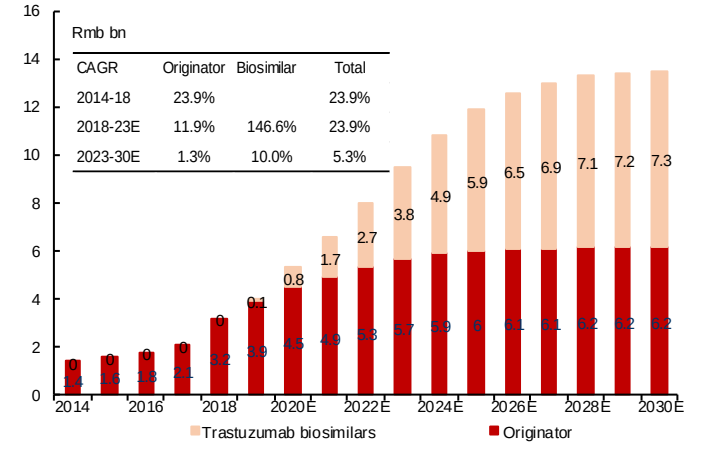
Source: F&S, CMBIS

Of China's five largest biosimilars, Henlius developed four. Core biosimilars developed by Henlius include a MabThera (rituximab) biosimilar, a Herceptin (trastuzumab) biosimilar, a Humira (adalimumab) biosimilar and an Avastin (bevacizumab) biosimilar.

Rituximab biosimilar market expected to be RMB2.7bn in 2023E in China. Henlius's HLX01 has received launching approval from NMPA on 22 Feb 2019, and being the first biosimilar developed in China in accordance with the Biosimilar Guidelines. According to F&S, China's rituximab biosimilar market is expected to grow at a CAGR of 54.8% from 2018 to ~RMB2.7bn in 2023E. Rituximab was added to the NRDL in 2017 and to the NEDL in Nov 2018, with a promising market potential.

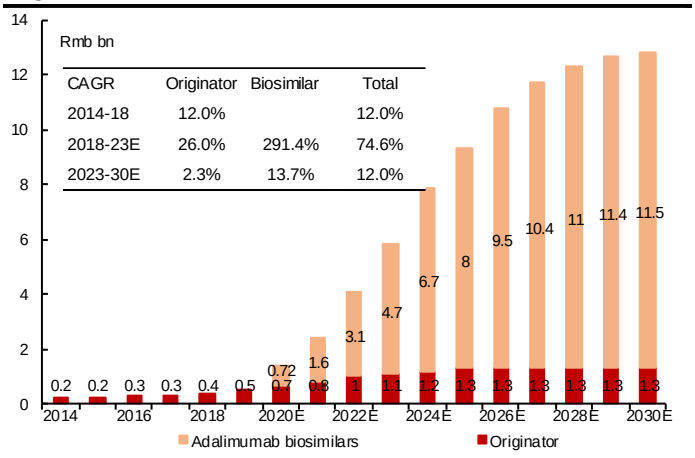
Trastuzumab biosimilar market expected to be RMB3.8bn in 2023E in China. Henlius conducted a multi-jurisdictional Phase 3 clinical trial for HLX02 with respect to the HER2+ metastatic breast cancer indication and has filed NDA to NMPA and EMA. The first trastuzumab biosimilar is expected to go to market by 2019. According to F&S, China's trastuzumab biosimilar market is expected to grow at 146.6% CAGR to~RMB3.8bn in 2023E mainly driven by more affordable drugs. Trastuzumab was also added to the 2017 NRDL and the 2018 NEDL.

Figure 42: China trastuzumab market forecast



Source: F&S, CMBIS

Figure 43: China adalimumab market forecast

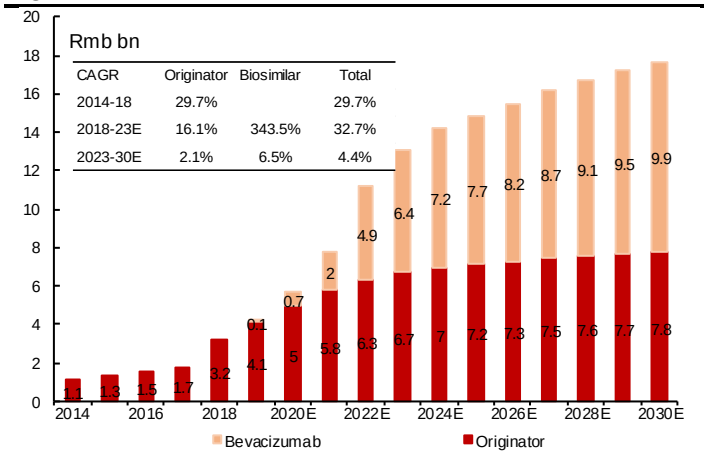


Source: F&S, CMBIS

Adalimumab biosimilar market expected to be RMB4.7bn in 2023E in China. Henlius has submitted HLX03's NDA to NMPA in Jan 2019. The first adalimumab biosimilar is expected to go to market by 2019. According to F&S, China's adalimumab biosimilar market is expected to grow at 291.4% in 2018-23E to ~RMB4.7bn in 2023E.

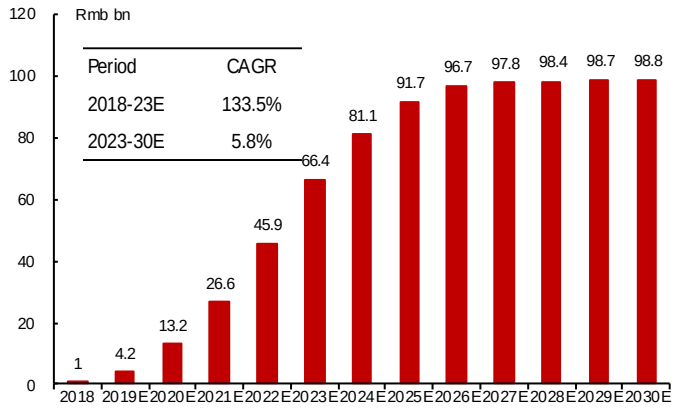
Bevacizumab biosimilar market expected to be RMB6.4bn in 2023E in China. Henlius has entered a Phase 3 clinical trial for HLX04 with respect to the metastatic colorectal cancer indication. The first bevacizumab biosimilar is expected to go to market by 2019. According to F&S, China's bevacizumab biosimilar market is expected to grow at 343.5% CAGR to ~RMB6.4bn in 2023E. Bevacizumab was added to the NRDL in 2017, which paved way for payment affordability.

Figure 44: China bevacizumab market forecast



Source: F&S, CMBIS

Figure 45: China PD-1/ PD-L1 inhibitors market forecast



Source: F&S, CMBIS

In addition to biosimilars, Henlius is also developing bio-innovative drugs, including HLX07, a cetuximab biobetter targeting EGFR, and HLX10, a novel PD-1 inhibitor and the combination therapies as well.

Cetuximab market expected to be RMB2.0bn in 2023E in China. Henlius has entered Phase 1b/2 clinical trials for HLX07. China's cetuximab market remained stable at~RMB0.3bn in recent years, primarily due to its high price. After Erbitux (cetuximab) biosimilars or biobetters are launched in China, and with ongoing additions of new drugs to the NRDL, the cetuximab market is expected to grow significantly. According to F&S, cetuximab sales revenue in China is expected to grow at 31.5% CAGR from 2017 to ~RMB2.0bn in 2023E, and further grow at a CAGR of 8.3% to reach RMB3.4bn in 2030E.

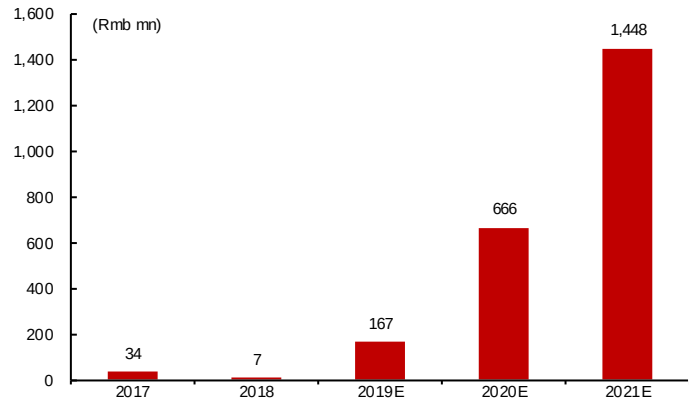
China's PD-1/PD-L1 inhibitor market expected to reach RMB98.8bn by 2030E, driven by indication expansion and more available drugs. Henlius has entered a Phase 1a clinical trial for HLX10. According to NMPA, as at 31 May 2019, five PD-1 inhibitors had been launched in China, namely Nivolumab from BMS, Pembrolizumab from Merck, Toripalimab from Junshi, Camrelizumab from Hengrui and Sintilimab from Innovent Biologics. BeiGene's Tislelizumab has filled NDA and is pending for CDE review. China's PD-1/PD-L1 inhibitor market is expected to grow rapidly in the coming years driven by more approved drugs and indication expansion as various types of cancers are responsive to PD-1/PD-L1 inhibitor. PD-1/PD-L1 sales in China is expected to grow at 133.5% CAGR of from 2018 to RMB66.4bn in 2023E, and further grow at 5.8% CAGR to reach RMB98.8bn in 2030E.

Financial Analysis

We estimate Henlius to turn profitable from 2021E

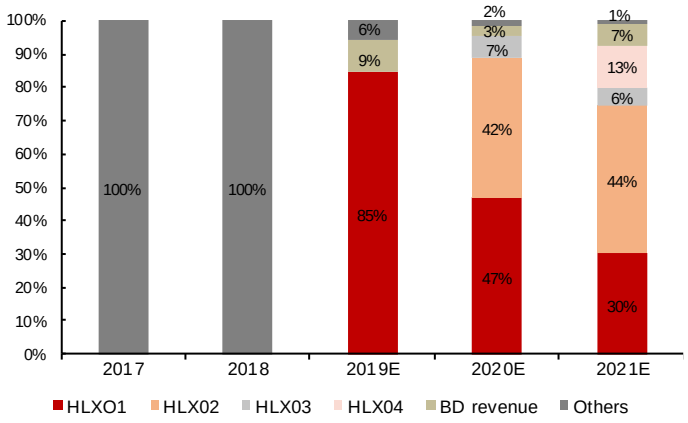
We forecast risk-adjusted revenue of RMB167mn/ RMB666mn/ RMB1,448mn in FY19E/20E/21E, mainly driven by HLX01, which was launched to market in 2Q19, and three core biosimilar drugs (HLX02, HLX03 and HLX04). We expect HLX02/ HLX03 to launch in 2020E and HLX04 in 2021E with probability of success (PoS) of 90%/90%/72%. We forecast net loss of RMB319mn/ RMB171mn in FY19E/20E and net profit of RMB198mn in FY21E. The first profitable year is estimated to be 2021E.

Figure 46: Revenue forecasts



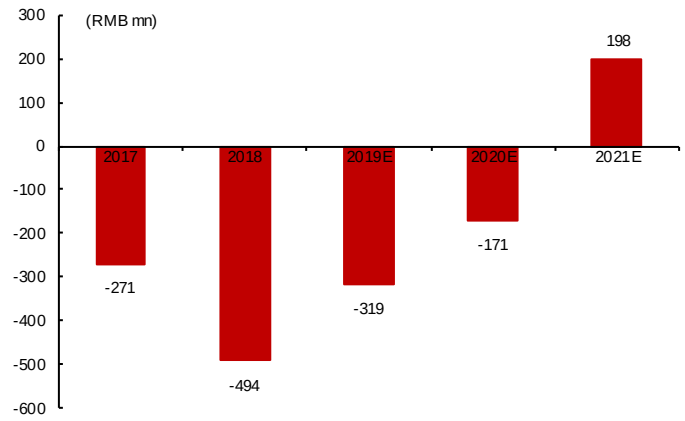
Source: Company data, CMBIS estimates

Figure 47: Revenue forecast breakdown



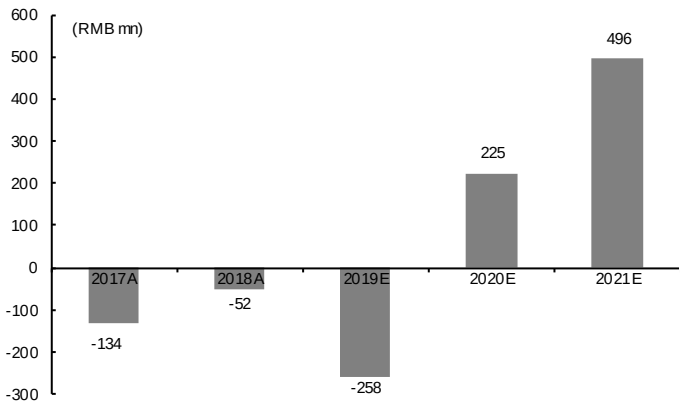
Source: Company data, CMBIS estimates

Figure 48: Expect Henlius to turn profitable from 2021E



Source: Company data, CMBIS estimates

Figure 49: Operating cash flow forecasts



Source: Company data, CMBIS estimates

Growth mainly driven by four core biosimilars in late stage

HLX01 for NHL has been commercialized in May 2019. We expect HLX01 to record total sales of RMB269mn/ RMB675mn/ RMB980mn in FY19E/20E/21E, of which RMB141mn/ RMB313mn /RMB439mn will be recorded by Henlius given the profit split agreement with Fosun Pharma. Besides, HLX01 is currently conducting Phase 3 trial on RA and we expect this indication to be approved in 2021E.

Figure 50: HLX01 sales forecasts and key assumptions

	2017A	2018A	2019E	2020E	2021E	2022E	2023E
HLX01 rituximab biosimilar							
ASP of MabThera, 100mg/ vial (RMB)	3,080	2,418	2,297	1,953	1,913	1,875	1,838
Price erosion %		*-21%*	*-5%*	*-15%*	*-2%*	*-2%*	*-2%*
ASP of HLX01, 100mg/ vial (RMB)	0	0	1,398	1,367	1,339	1,313	1,286
Price discount to MabThera	*0%*	*0%*	*39%*	*30%*	*30%*	*30%*	*30%*
# of vials per NHL treatment	22	34	36	42	49	49	56
# of patients on HLX01-NHL ('000)	0	0	6	13	16	20	23
HLX01-NHL's rituximab market share by volume	*0%*	*0%*	*15%*	*30%*	*35%*	*40%*	*45%*
Gross ex-factory sales-HLX01-NHL (RMB mn)	**0**	**0**	**269**	**675**	**946**	**1,112**	**1,471**
PoS%	0%	0%	100%	100%	100%	100%	100%
HLX01-NHL PoS-adjusted sales (RMB mn)	**0**	**0**	**269**	**675**	**946**	**1,112**	**1,471**
# of vials per RA treatment	30	30	30	30	30	30	30
# of patients on HLX01-RA ('000)	0	0	0	0	1	2	4
HLX01 RA patient share	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*
Gross ex-factory sales-HLX01-RA (RMB mn)	**0**	**0**	**0**	**0**	**47**	**77**	**114**
PoS %	0%	0%	72%	72%	72%	72%	72%
HLX01-RA PoS-adjusted sales (RMB mn)	**0**	**0**	**0**	**0**	**34**	**56**	**82**
HLX01-NHL+RA PoS-adjusted sales (RMB mn)	**0**	**0**	**269**	**675**	**980**	**1,168**	**1,553**
Revenue to Henlius after split with Fosun Pharma (RMB mn)	**0**	**0**	**141**	**313**	**439**	**488**	**646**

Source: Company data, CMBIS estimates

HLX03 is under priority review by CDE. We apply a 90% probability for obtaining approval and expect HLX03 to record risk-adjusted revenue of RMB45mn/ RMB80mn in FY20E/FY21E, after split with Jiangsu Wanbang.

Figure 51: HLX03 sales forecasts and key assumptions

	2017A	2018A	2019E	2020E	2021E	2022E	2023E
HLX03 adalimumab biosimilar							
ASP of Humira (RMB)	7,670	7,593	6,074	3,160	3,065	2,973	2,884
Price erosion %		*-1.0%*	*-20.0%*	*-48.0%*	*-3.0%*	*-3.0%*	*-3.0%*
ASP of HLX03 (40mg/ vial)(RMB)	0	0	0	2,212	2,146	2,081	2,019
Price discount to Humira				*30.0%*	*30.0%*	*30.0%*	*30.0%*
# of vials per treatment	21	21	21	21	21	21	21
# of patients on HLX03 ('000)	0	0	0	2	4	12	24
HLX03's RA/AS/PS patient share	*0%*	*0%*	*0%*	*1%*	*2%*	*5%*	*8%*
Gross ex-factory sales-HLX03 (RMB mn)	**0**	**0**	**0**	**69**	**161**	**464**	**896**
Revenue to Henlius after split with Wanbang (RMB mn)	**0**	**0**	**0**	**50**	**89**	**211**	**368**
PoS %	0%	0%	90%	90%	90%	90%	90%
PoS-adjusted sales after split (RMB mn)	**0**	**0**	**0**	**45**	**80**	**190**	**331**

Source: Company data, CMBIS estimates

HLX02 has filed NDA in Apr 2019 and is expect to be launched in 2020E. We apply a 90% probability for successfully getting approval and forecast HLX02 to generate risk-adjusted revenue of RMB279mn/ RMB639mn in FY20E/FY21E.

HLX04 is in Phase 3 study on mCRC. We expect it to get approval in 2021E. And we apply a PoS rate of 72% and forecast it to generate risk-adjusted sales of RMB183mn in FY21E.

Figure 52: HLX02 sales forecasts and key assumptions

	2017A	2018A	2019E	2020E	2021E	2022E	2023E
HLX02 trastuzumab biosimilar							
ASP of Herceptin (RMB)	7,600	7,600	7,448	7,270	7,125	6,982	6,842
Price erosion %		*0.0%*	*-2.0%*	*-2.4%*	*-2.0%*	*-2.0%*	*-2.0%*
ASP of HLX02 (440mg/ vial)(RMB)	0	0	0	5,089	4,987	4,887	4,790
Price discount to Herceptin	*0%*	*0%*	*0%*	*30%*	*30%*	*30%*	*30%*
# of vials per BC treatment	13	13	13	15	15	15	15
# of BC patients on HLX02 ('000)	0	0	4	10	20	25	28
HLX02-BC's trastuzumab market share	*0%*	*0%*	*0%*	*10%*	*20%*	*35%*	*40%*
Gross ex-factory sales-HLX02-BC (RMB mn)	**0**	**0**	**0**	**282**	**644**	**1,275**	**1,564**
# of vials per GC treatment	7	7	7	7	7	8	8
# of GC patients on HLX02 ('000)	0	0	0	1	2	4	5
HLX02-GC's trastuzumab market share by volume	*0%*	*0%*	*0%*	*10%*	*20%*	*35%*	*40%*
Gross ex-factory sales-HLX02-GC (RMB mn)	**0**	**0**	**0**	**28**	**66**	**133**	**173**
PoS %	90%	90%	90%	90%	90%	90%	90%
HXL02-PoS-adjusted sales (RMB mn)	**0**	**0**	**0**	**279**	**639**	**1,267**	**1,563**

Source: Company data, CMBIS estimates

Figure 53: HLX04 sales forecasts and key assumptions

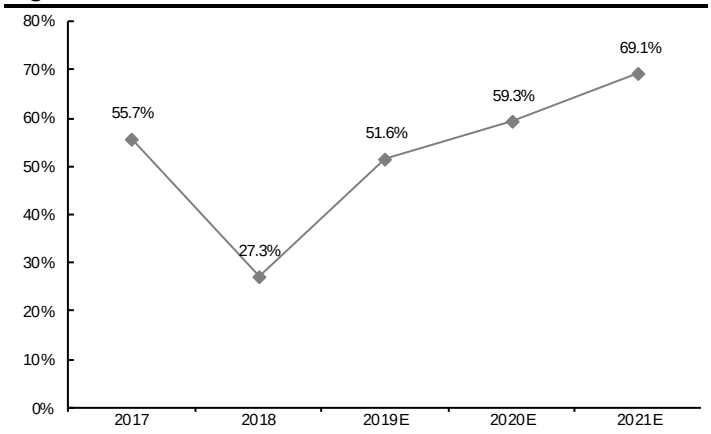
	2017A	2018A	2019E	2020E	2021E	2022E	2023E
HLX04 Bevacizumab biosimilar							
ASP of Avastin (RMB), 100mg/vial (RMB)	3,455	1,998	1,934	1,876	1,820	1,765	1,712
Price erosion %		*-42.2%*	*-3.2%*	*-3.0%*	*-3.0%*	*-3.0%*	*-3.0%*
ASP of HLX04, 100mg/ vial (RMB)	0	0	0	0	1,274	1,236	1,199
Price discount to Avastin	*0%*	*0%*	*0%*	*0%*	*30%*	*30%*	*30%*
# of vials per mCRC treatment	37	37	39	39	39	39	39
# of patients on HLX04-mCRC ('000)	0	0	0	0	2	5	9
HLX04-mCRC's Bevacizumab market share by volume	*0%*	*0%*	*0%*	*0%*	*10%*	*20%*	*30%*
# of vials per NSCLC treatment	88	89	91	94	94	94	94
# of patients on HLX04-NSCLC ('000)	0	0	0	0	1	4	8
HLX04-NSCLC's Bevacizumab market share by volume	*0%*	*0%*	*0%*	*0%*	*5%*	*10%*	*20%*
Ex-factory sales-HLX04 (RMB mn)	**0**	**0**	**0**	**0**	**254**	**590**	**1,205**
PoS %	72%	72%	72%	72%	72%	72%	72%
HLX04-PoS-adjusted sales (RMB mn)	**0**	**0**	**0**	**0**	**183**	**425**	**868**

Source: Company data, CMBIS estimates

GPM expected to gradually improve. We forecast GPM to be 51.6%/ 59.3%/ 69.1% in FY19E/20E/21E due mainly to product launch and economies of scale.

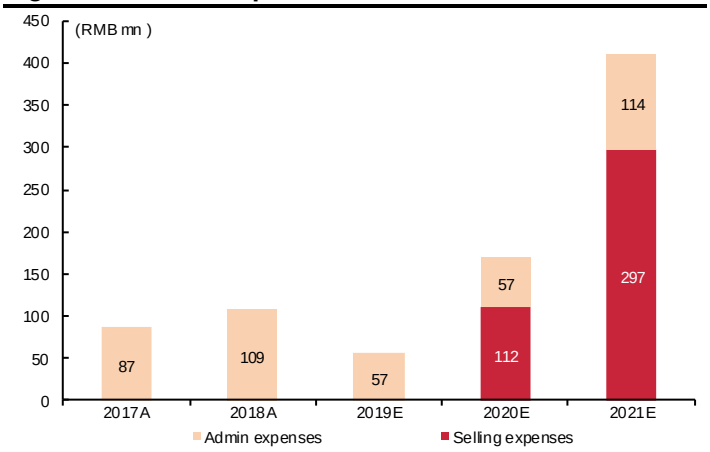
S&G to rise over time. We forecast selling expenses to be RMB112mn /RMB297mn in FY20E/21E, or 16.7%/20.5% of total sales, given that HLX01 and HLX03's marketing expenses will be paid by Fosun, and Henlius will be only responsible for HLX02 and HLX04's marketing activities through its own marketing team.

Figure 54: GPM forecasts



Source: Company data, CMBIS estimates

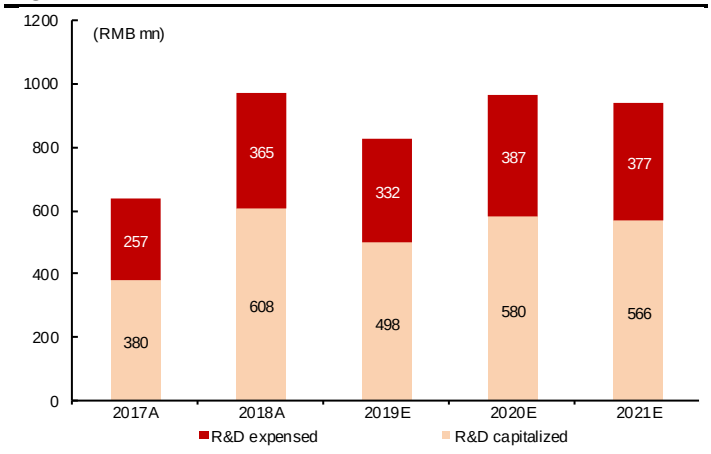
Figure 55: SG&A expenses forecasts



Source: Company data, CMBIS estimates

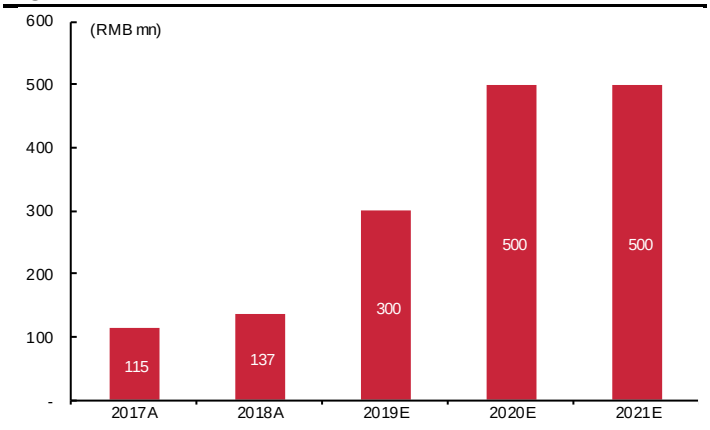
R&D and CAPEX to stay high. Henlius invested overall R&D spending (both capitalized and expensed) of RMB637mn /RMB973mn in FY17/FY18, of which RMB257mn /RMB365mn are expensed, respectively. We expect R&D spending to stay high going forward, given HLX04 in Phase 3 trials, PD-1 and PD-1 combo in Phase 2/3 trials, and other biosimilars and bio-innovative drugs in early stage. We expect overall R&D spending in FY19/FY20E/FY21E to be RMB830mn /RMB967mn /RMB943mn and expensed R&D to be RMB332mn /RMB387mn /RMB377mn. We estimate capital expenditures to be RMB300mn / RMB500mn / RMB500mn in FY19E/20E/21E, mainly for the construction of new factory in Songjiang, Shanghai.

Figure 56: R&D cost forecasts



Source: Company data, CMBIS estimates

Figure 57: CAPEX forecasts of PP&E



Source: Company data, CMBIS estimates

Financial Statments

Income statement

YE Dec 31 (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
Revenue	**34**	**7**	**167**	**666**	**1,448**
Drug sales	-	-	141	638	1,341
BD sales	-	-	15	19	97
Other income	34	7	10	10	10
Cost of sales	(15)	(5)	(81)	(271)	(447)
Gross profit	**19**	**2**	**86**	**395**	**1,001**
Distribution expenses	-	-	-	(112)	(297)
Administrative expenses	(87)	(109)	(57)	(57)	(114)
R&D expenses	(257)	(365)	(332)	(387)	(377)
Operating profit	**(326)**	**(472)**	**(303)**	**(161)**	**213**
Finance income/ (cost)	(55)	(58)	(32)	(26)	(20)
Exceptional	1	30	15	15	15
Pre-tax profit	**(380)**	**(500)**	**(319)**	**(171)**	**208**
Profit tax	(4)	(5)	-	-	(10)
Minority interest	114	11	-	-	-
Net profit	**(271)**	**(494)**	**(319)**	**(171)**	**198**

Cash flow summary

YE Dec 31 (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
PBT	**(380)**	**(500)**	**(319)**	**(171)**	**208**
Depreciation & amortization	26	29	114	171	254
Change in working capital	40	302	(85)	199	25
Income tax paid	(4)	(5)	-	-	(10)
Others	184	121	32	26	20
Net cash from operating	**(134)**	**(52)**	**(258)**	**225**	**496**
Capex	(115)	(137)	(300)	(500)	(500)
Acquisition of intangible asset	(356)	(598)	(498)	(580)	(566)
Other	-	-	-	-	-
Net cash from investing	**(472)**	**(735)**	**(798)**	**(1,080)**	**(1,066)**
Loan to related party	425	(575)	-	-	-
Net proceeds from shares	178	2,639	2,777	-	-
Bank borrowing	(18)	296	-	(100)	(100)
Acquisition of non-controlling	-	(635)	-	-	-
Interest paid	(43)	(45)	(32)	(26)	(20)
Net cash from financing	**541**	**1,679**	**2,745**	**(126)**	**(120)**
Net change in cash	(65)	892	1,689	(981)	(689)
Cash at the beginning of the	123	59	959	2,648	1,667
Exchange difference	(0)	9	-	-	-
Cash at the end of the year	**59**	**959**	**2,648**	**1,667**	**977**

Balance sheet

YE Dec 31 (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
Non-current assets	**1,252**	**2,008**	**2,692**	**3,601**	**4,413**
Fixed asset	290	324	579	998	1,359
Intangible assets	772	1,383	1,812	2,301	2,752
Other non-current assets	189	301	301	301	301
Current assets	**233**	**1,087**	**2,777**	**1,889**	**1,281**
Cash	59	959	2,648	1,667	977
Inventories	25	25	7	37	61
Trade and bills receivables	20	7	27	89	147
Prepayments, deposits	125	90	90	90	90
Pledged cash	4	6	6	6	6
Current liabilities	**1,212**	**533**	**475**	**537**	**595**
Borrowings	596	143	143	143	143
Trade and other payables	74	85	27	89	147
Other current liabilities	542	305	305	305	305
Non-current liabilities	**349**	**759**	**734**	**863**	**813**
Borrowings	163	385	385	285	185
Other non-current liabilities	186	373	349	578	627
Total net assets	**(76)**	**1,803**	**4,260**	**4,089**	**4,287**
Minority interest	**4**	**-**	**-**	**-**	**-**
Shareholders' equity	**(80)**	**1,803**	**4,260**	**4,089**	**4,287**

Key ratios

YE Dec 31	FY17A	FY18A	FY19E	FY20E	FY21E
Sales mix (%)					
Drug sales	-	-	84.8	95.7	92.6
BD sales	-	-	9.2	2.8	6.7
Other income	100.0	100.0	6.0	1.5	0.7
Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**
Profit & loss ratios (%)					
Gross margin	56	27	52	59	69
EBITDA margin	N/A	N/A	N/A	2	32
Pre-tax margin	N/A	N/A	N/A	N/A	14
Net margin	N/A	N/A	N/A	N/A	14
Effective tax rate	N/A	N/A	-	-	5
Balance sheet ratios					
Current ratio (x)	0.2	2.0	5.9	3.5	2.2
Trade receivables turnover	-	50	50	50	50
Trade payables turnover	-	120	120	120	120
Inventory turnover days	30	50	50	60	60
Net debt to total equity ratio	112.9	Net cash	Net cash	Net cash	Net cash
Returns (%)					
ROE	N/A	N/A	N/A	N/A	4.8
ROA	N/A	N/A	N/A	N/A	3.6
Per share data					
EPS (RMB)	(0.77)	(1.16)	(0.59)	(0.32)	0.37
DPS (RMB)	-	-	-	-	-
BVPS (RMB)	(0.2)	4.2	7.9	7.6	8.0

Source: Company data, CMBIS estimates

Valuation

As Henlius is a pre-revenue biotechnology company, it relies on future cash flow from drugs sales, which is driven by drug sales and products on pipeline. DCF would be a reasonable valuation method for Henlius.

We derive TP of HK$61.12 based on a 12-year DCF valuation (WACC: 10.03%, terminal growth rate: 4.0%). We employed a WACC of 10.03%, which is higher than that of HK listed peers due to higher risk, and terminal growth rate of 4%, which is consistent with Chinese pharma companies.

Figure 58: Base case valuation on risk-adjusted DCF valuation

	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn	RMB mn
EBIT	(303)	(161)	213	852	1,624	2,258	2,570	2,792	3,169	3,472	3,660	3,856
Less: Tax	0	0	(10)	(85)	(244)	(339)	(386)	(419)	(476)	(521)	(549)	(579)
Depreciation and amortisation	114	171	254	327	384	434	468	497	492	485	479	473
CAPEX	(798)	(1,080)	(1,066)	(922)	(900)	(700)	(700)	(450)	(400)	(400)	(400)	(400)
Change in working capital	(85)	199	25	9	(90)	(64)	(154)	(75)	(74)	(77)	(37)	(44)
FCF	(1,072)	(871)	(585)	180	775	1,588	1,798	2,345	2,711	2,959	3,153	3,307
Terminal value												57,085
FCF+Termincal value		(871)	(585)	180	775	1,588	1,798	2,345	2,711	2,959	3,153	60,392
Discount factor		0.91	0.83	0.75	0.68	0.62	0.56	0.51	0.47	0.42	0.38	0.35
PV of FCF		(791)	(483)	135	529	985	1,014	1,201	1,263	1,252	1,213	21,114
Present value of enterprise (RMB mn)	27,432											
Debt & Preferred Stock (RMB mn)	528											
Bank deposit and pledged cash (RMB mn)	2,654											
Equity value (RMB mn)	29,558											
Value per share (RMB)	**54.83**											
Value per share (HK$)	**61.12**											
WACC	10.03%											
Terminal growth rate	4.0%											

Source: CMBIS estimates

Figure 59: Corporate value sensitivity analysis (HK$ mn)

		WACC						
		8.5%	9.0%	9.5%	10.0%	10.5%	11.0%	11.5%
	2.5%	69.16	62.68	57.17	52.42	48.29	44.68	41.49
	2.0%	65.32	59.54	54.56	50.24	46.46	43.12	40.16
	3.5%	79.12	70.68	63.67	57.78	52.75	48.43	44.66
Terminal growth rate	4.0%	85.76	75.87	67.81	**61.12**	55.49	50.70	46.57
	4.5%	94.04	82.20	72.76	65.07	58.69	53.32	48.74
	5.0%	104.68	90.12	78.82	69.81	62.47	56.38	51.25
	5.5%	118.83	100.27	86.38	75.59	67.00	59.98	54.17

Source: CMBIS estimates

Investment Risks

No track record of successful commercialization

As of 30 Jun, 2019, Henlius recorded revenue of RMB38.1mn/ RMB33.9mn/ RMB17.04mn in FY16/FY17/1H19. HLX01, rituximab biosimilar for NHL was approved by the NMPA on 22 Feb 2019, available for sale and enjoys the same reimbursement policy as the originator. Henlius may fail to generate sales as expected, because 1) smaller-than-expected addressable market may constrain sales scale, 2) insurance coverage and reimbursement may be limited in certain markets for some drug candidates, and 3) subject to regulatory price control or medical insurance reimbursement caps.

However, at the beginning, Henlius received strong support from its holding company Fosun Pharma. It entered into commercialising agreements with Fosun Pharma and Wanbang, who is in charge of commercialisation activities and costs for HLX01 and HLX03, respectively and agree to reimburse a portion of the clinical trial expenditure. Upon their successful commercialisation, such partners will share a portion of the profit with Henlius at 1:1 split ratio.

Medical cost control may lead to further price cut

Adequate coverage and reimbursement from government healthcare programmes are critical to new drug acceptance in China. The Ministry of Human Resources and Social Security of the PRC regularly reviews the inclusion or removal of drugs from NRDL, NEDL, or provincial medical insurance catalogues, based on a number of factors, including price and efficacy. Products included in the NRDL are typically generic and essential drugs. Innovative drugs have historically been more limited on their inclusion in the NRDL due to their initial higher price and the limited affordability of NRDL. There can be no assurance that any of Henlius's drug candidates will be included in the NRDL. Drugs may become subject to regulatory price control and more stringent insurance reimbursement caps.

Limited experience in manufacturing biologics drugs on a large commercial scale

The manufacture of biologics is a highly exacting and complex process. Any improper operation in manufacturing may lead to additional expenses or discard. Since Henlius has no manufacturing experience on commercial scales, it may not be able to supply products at a cost or in quantities or in a timely manner necessary, due to 1) longer-than-expected time to ramp up production, 2) insufficient orders, 3) low success rate of products that meet regulatory requirements, and 4) inability to expand capacity as anticipated.

Fierce competition from peers in China and overseas

The biologics market is highly competitive, characterised by extensive R&D, technological change, innovations, new applications and evolving industry standards, etc. This high level of competition is expected to increase over time. The core biosimilar drugs developed by Henlius faced fierce competition from domestic peer companies, as some of whose drugs have entered into last stage. Furthermore, those competitors may have greater financial and R&D resources, greater pricing flexibility, and more extensive technical capabilities and more experienced sales team. Henlius may be unable to generate target profits, resulting from 1) failing in introducing new competitive drugs timely, 2) higher-than-expected price cut of originators, exerting price pressure on biosimilars.

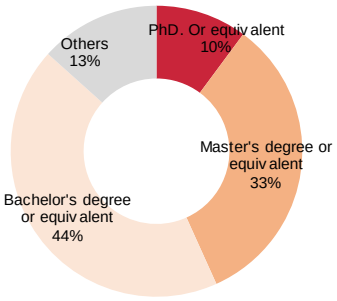
Appendix 1: Company Profile

Figure 60: # of employees by function, as of 30 Jun, 2019

Function	Number	% of total
Management and administrative	114	13.0%
Research and development	260	29.7%
Quality and technical support	168	19.2%
Manufacturing	171	19.6%
Clinical medical affairs	161	18.4%
Total	874	100.0%

Source: Company data, CMBIS

Figure 61: Education background of employees, as of 31 Mar, 2019



Source: Company data, CMBIS

Figure 62: Awards

Year	Award	Issuing body
2016	High and New Technology Enterprises (“高新技术企业”)	Shanghai Science & Technology Committee Shanghai Municipal Finance Bureau, the Shanghai Municipal Office of the State Administration of Taxation and the Shanghai Municipal Bureau of Local Taxation
2017	Best Bioprocessing Excellence in China	IMAPAC
2017	Leading Innovations in Cutting-edge Technologies for Novel mAb Development & Production	IMAPAC
2017	2017 Future Star in the China Pharma Industry	Deloitte Touche Tohmatsu
2018	Asia Biotech of 2017	Annual BioPharma Industry Awards
2018	Bioprocessing Innovations in Single-Use Manufacturing in China	IMAPAC
2018	the Most Promising Enterprises in China (“中国最具潜力企业”)	Ernst & Young
2018	China Top 50 Investments for Value (“中国最具投资价值企业 50 强”)	Venture 50
2018	Future Stars (“未来之星”)	China Entrepreneur

Source: Company data, CMBIS

Appendix 2: Glossary

Figure 63: Glossary

Term	Explanation
Adverse event	Any untoward medical occurrence in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which does not necessarily have a causal relationship with the treatment.
API	The substance in a pharmaceutical drug that is biologically active when administered.
AUC	The area under the curve, a measure of how much of a drug is in a patient's system over a given time period. In order to calculate the AUC.
B cell	A type of white blood cell that differs from other types of lymphocytes by expressing B cell receptors on its surface, and responsible for producing antibodies.
biobetters	Improved versions of existing reference drugs in terms of efficacy and safety
bio-innovative drugs	New drugs that are not marketed anywhere in the world or biosimilars for which the reference drugs are approved for certain indications in other jurisdictions but not in China
biosimilars	Biological drugs which are designed to have the same amino acid sequence and the equivalent (but not identical or clinical better) active properties as compared to reference drugs that have already received marketing approvals.
cGMP	Current good manufacturing practice
chemotherapy	A category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardised regimen
CHOP	Chemotherapy regimen consisting of cyclophosphamide, hydroxydaunomycin, oncovin and prednisone
CI	Confidence interval
Cmax	Maximum measured serum concentration
cohort	A group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
CR	Complete response
DCR	Disease control rate
DFS	Disease-free survival rate
DLBCL	CD20-positive diffuse large B cell lymphoma, a common subset of NHL
DLT	Dose-limiting toxicity
DoR	Duration of response
EFS	Event-free survival rate
GMP	Good manufacturing practice
H-CHOP	HLX01(rituximab) combined with CHOP
HER2+	HER2-positive
immunotherapy	Use of the immune system to treat disease
MTD	Maximum tolerated dose
ORR	Objective response rate
PR	Partial response progression free survival or PFS
R+M	Rituximab combined with methotrexate
R-CHOP	MabThera (rituximab) with CHOP
SAEs	Any untoward medical occurrence in a patient during clinical trials that results in death, is life-threatening, requires inpatient hospitalisation, disability/incapacity, etc.

Source: Company data, CMBIS

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