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Medical devices |
Company Research
28 March 2023

Leading cancer screening product developer in China

New Horizon Health (06606:HK)

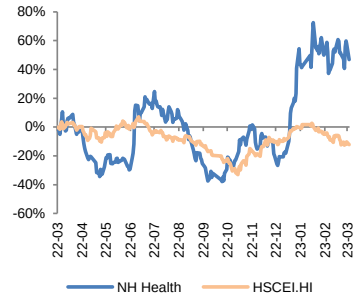
BUY

Initiation of coverage

Market Data: 20 March 2023

Closing price (HK$)	31.55
HSCEI	6,470
52-week high/Low (HK$)	38.95/12.70
Market Cap (HK$m)	14,436
Shares outstanding (m)	458
Exchange Rate (Rmb-HK$)	0.88

Price Performance Chart:



Source: Bloomberg

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New Horizon Health is the first biotech company in China, with a focus on developing and commercialising cancer screening products. At present, the company has launched three commercialised products, including ColoClear and Pupu Tube for colorectal cancer screening and UU tube for Helicobacter pylori (Hp) screening. In addition, the company has other products and study under development, including CerviClear for cervical cancer screening, LiverClear for liver cancer screening, Yibiqing for nasopharyngeal cancer screening, PANDA study for pan-cancer early screening and diagnosing and other early-stage products under development. With the sales ramp-up of three key commercialized products, we expect the company's revenue to reach Rmb1.43bn in 23E, Rmb2.06bn in 24E and Rmb3.16bn in 25E, growing at a Cagr of 61% in 2022-25E.

Promising cancer screening market in China. According to the global cancer statistics from the International Agency for Research on Cancer (IARC), in terms of the number of new cancer cases, the top five cancer types are breast cancer, lung cancer, colorectal cancer, prostate cancer and gastric cancer, which accounted for 11.7%, 11.4%, 11.0%, 7.3% and 5.6% of the total new cancer cases, respectively. By countries, both the cancer incidence (4.57m) and mortality (3.00m) of China ranked first in the world in 2020, representing 23.7% and 30.2% of the total. According to Frost & Sullivan, the Chinese market size of screening for colorectal cancer, gastric cancer, and cervical cancer stood at Rmb4.6bn, Rmb3.7bn and Rmb3.1bn in 2022, respectively. With the increasing awareness of cancer screening, it expects those markets to grow at Cagrs of 19.6%, 20.2% and 19.7% in 2020-2030E, respectively.

Fast sales ramp-up of key commercialised products. ColoClear and Pupu Tube used for colorectal cancer screening were approved by NMPA as Class III medical device and Class II medical device in November 2020 and March 2018 respectively, with ColoClear being the only approved screening product in China targeting c.120m population with high risk of colorectal cancer in China, and Pupu Tube being the first and only approved self-examined screening product in China. In June 2022, ColoClear successfully entered Hong Kong market through a partnership with Prenetics. In 2022, the revenue of ColoClear and Pupu Tube reached Rmb360m (+266% YoY) and Rmb200m (+74%). With the sales ramp-up in hospitals, we expect the revenue of ColoClear to grow at a Cagr of 81% in 2022-2025E. In addition, with the growing awareness of early cancer screening and increasing sales in DTC channel, we expect the revenue of Pupu Tube to grow at a Cagr of 33% in 2022-2025E. Besides, the company's third commercialized product, UU Tube, was approved by the NMPA as Class III medical device in January 2022. After being launched in the market, UU Tube realised fast sales ramp up, with sales reaching Rmb210m in 2022, and we expect it to grow at a Cagr of 42% in 2022-2025E.

Multi-cancer screening products matrix, focusing on gastric cancer, cervical cancer and liver cancer. Currently, the company's pipeline includes CerviClear for cervical cancer screening, LiverClear for liver cancer screening, NPClear for nasopharyngeal cancer screening, and a pan-cancer early detection program (PANDA). In November 2022, CerviClear has completed the enrolment of first patient, formally entering into a registrational trial, which is a large-scale prospective multi-centre registration trial for 3 years, with an estimated total enrolment of c.20,000 people. In addition, LiverClear is expected to initiate a prospective multi-centre clinical trial in 1Q23.

Initiate with BUY. Considering the sales ramp-up of three key commercialised products, we forecast its revenue to reach Rmb1.43bn in 23E (+87% YoY), Rmb2.06bn in 24E (+44% YoY) and Rmb3.16bn in 25E (+54% YoY). Based on a discounted cash flow (DCF) model, we arrive at a target price of HK$55.1. With 75% upside, we initiate coverage with a BUY recommendation.

Risks. Rising competition in the cancer screening market; lower-than-expected penetration rate; delay of pipeline progress.

Financial summary and valuation

	2021	2022	2023E	2024E	2025E
Revenue (Rmbm)	213	765	1,430	2,058	3,163
Growth (YoY %)	201.50	259.54	86.88	43.95	53.71
Net profit (Rmbm)	(3,085)	(80)	(43)	234	556
Growth (YoY %)	-	-	-	-	137.97
EPS (Rmb)	(8.15)	(0.19)	(0.09)	0.51	1.22
ROE (%)	(145.08)	(3.79)	(1.55)	7.75	15.58
PE (x)	(3.41)	(146.21)	(294.62)	54.36	22.84
PB (x)	4.94	5.53	4.57	4.21	3.56

Note: EPS is calculated as the net profit attributable to shareholders divided by weighted average number of shares.

投资要点：

诺辉健康是国内首家专注于开发和商业化癌症筛查产品的生物科技公司。目前，公司共有三款商业化产品（常卫清、噗噗管和幽幽管），以及其他在研产品/项目，其中三款商业化产品包括针对结直肠癌筛查的常卫清和噗噗管，以及针对幽门螺旋杆菌筛查的幽幽管。此外，在研产品/项目，包括宫证清（宫颈癌）、苷证清（肝癌）、易必清（鼻咽癌），以及泛癌种早筛早诊队列 PANDA 研究项目等。随着公司三款商业化产品销售放量，我们预计 2023-2025 年公司收入分别为 14.30 亿元、20.58 亿元和 31.63 亿元，2022-2025 年复合增速为 61%。

国内癌症早筛市场前景广阔。根据国际癌症研究机构（IARC）的统计数据，2020 年全球新发病例数排名前五的癌种分别为乳腺癌、肺癌、结直肠癌、前列腺癌和胃癌，占比分别为 11.7%、11.4%、11.0%、7.3%和 5.6%。按国家来看，2020 年中国癌症新发病例数和死亡病例数均位于全球第一，分别为 457 万例和 300 万例，占比分别为 23.7%和 30.2%。根据弗若斯特沙利文的分析，2022 年中国结直肠癌、胃癌、宫颈癌筛查市场的规模分别为 46 亿元、37 亿元和 31 亿元。随着癌症筛查意识的的逐步提升，预计 2020-2030 年复合增速将分别为 19.6%、20.2%和 19.7%。

三款商业化产品快速放量。公司结直肠癌筛查产品常卫清和噗噗管分别于 2020 年 11 月和 2018 年 3 月获得 NMPA 的三类和二类医疗器械注册证，其中常卫清为国内唯一获批的针对中国约 1.2 亿结直肠癌高风险人群的早筛产品、噗噗管为国内首款且唯一获批的自测早筛产品。2022 年 6 月，常卫清通过 Prenetics 于香港成功上市。2022 年常卫清和噗噗管销售快速放量，收入分别为 3.6 亿元和 2.0 亿元，分别同比增长 266%和 74%。随着临床医院渠道收入占比的提升，我们预计 2022-2025 年常卫清收入复合增速为 81%。此外，考虑到癌症早筛意识和 DTC 渠道收入占比提升，我们预计 2022-2025 年噗噗管收入复合增速为 33%。此外，公司第三款商业化产品幽幽管于 2022 年 1 月获得 NMPA 三类医疗器械注册证，该产品上市后实现快速销售放量，2022 年幽幽管收入为 2.1 亿元，预计 2022-2025 年幽幽管的收入复合增速为 42%。

多癌种布局，聚焦胃癌、宫颈癌和肝癌。目前公司的在研产品/项目，包括宫证清（宫颈癌）、苷证清（肝癌）、易必清（鼻咽癌），以及泛癌种早筛早诊队列 PANDA 研究项目等。2022 年 11 月，宫证清完成首例患者入组，正式进入注册临床阶段。该试验为大规模前瞻性多中心注册临床试验，为期 3 年，预计入组总规模近 2 万人。苷证清预计于 2023 年第一季度启动前瞻性多中心临床试验。

首次覆盖给予买入评级。考虑到三款商业化产品的销售贡献，我们预计 2023-2025 年公司收入分别为 14.30 亿元、20.58 亿元和 31.63 亿元，分别同比增长 87%、44%和 54%。基于 DCF 模型，我们给予目标价为 55.1 港元，对应 75%的上涨空间，首次覆盖给予买入评级。

风险提示：癌症早筛市场竞争加剧；渗透率提升不及预期；研发管线进展不及预期。

Investment thesis

Earnings forecasts and valuation

Given New Horizon Health's leading position in China's cancer screening market, rising market penetration rate, and insufficient supply or inconvenient use of a gold standard of screening methods, such as colonoscopy procedures or urea breath tests, we expect the company's products to see a fast sales ramp-up. We forecast revenue of Rmb1.43bn in 23E, Rmb2.06bn in 24E and Rmb3.16bn in 25E, growing at a Cagr of 61% in 2022-25E.

In addition, considering the economy of scale and changes in the channel mix, we expect blended gross margin to reach 86.0% in 23E, 86.4% in 24E and 87.0% in 25E. Meanwhile, with the rising revenue contribution from hospitals, we expect the gross margin of ColoClear to reach 85.0% in 23E, 86.0% in 24E and 87.0% in 25E. As for the Pupu Tube and UU Tube, we expect the gross margin to remain stable at 82.1% and 90.7% in 2023-25E, with a relatively stable sales channel.

New Horizon Health is trading at 9x 23E PS and 6x 24E PS, vs 4x 23E PS and 4x 24E PS for its Hong Overseas peers, and 7x 23E PS and 6x 24E PS for A-share peers on average. We believe the company deserves a valuation premium to its Hong Kong-listed peers thanks to the scarcity of its business and its promising growth outlook.

Based on a discounted cash flow (DCF) model, we arrive at a target price of HK$55.1. With 75% upside, we initiate coverage with a BUY recommendation.

Key assumptions

Breaking down by products, we expect the revenue of ColoClear to reach Rmb750m in 23E, Rmb1.19bn in 24E and Rmb2.10bn in 25E, growing at a Cagr of 81% during 2022-25E, with the sales ramp-up in hospitals. In addition, with the growing awareness of early cancer screening and increasing sales in DTC channel, we expect the revenue of Pupu Tube to grow at a Cagr of 33% in 2022-2025E, reaching Rmb288m in 23E, Rmb372m in 24E and Rmb467m in 25E. Besides, we forecast sales of UU Tube to reach Rmb392m in 23E, Rmb492m in 24E and Rmb595m in 25E, growing at a Cagr of 42% in 2022-2025E. Given that the pipeline products and projects are in the early development stage, our earnings forecast of 2023-25E have not included CerviClear (cervical cancer), LiverClear (liver cancer), NPClear (nasopharyngeal cancer), etc.

How we differ from consensus

At present, cancer screening products are still in the early stage of development. Given the significant short supply of domestic colonoscopy equipment and professional detection personnel, and the company's first-mover advantage in China's cancer screening market, we are positive on the long-term growth potential of the company. We believe that the fast sales ramp-up of existing products and continued channel optimization will support rapid revenue growth.

Catalysts

1) Business: Rising contribution from hospitals and DTC; higher-than-expected sales ramp up.

2) Policy: CerviClear completed the patient enrollment in 23E; LiverClear to initiate the prospective clinical trials in 23E.

Risks

1) Business: Rising competition in the cancer screening market; lower-than-expected penetration rate.

2) Policy: Delay of pipeline progress.

1. Company at a glance

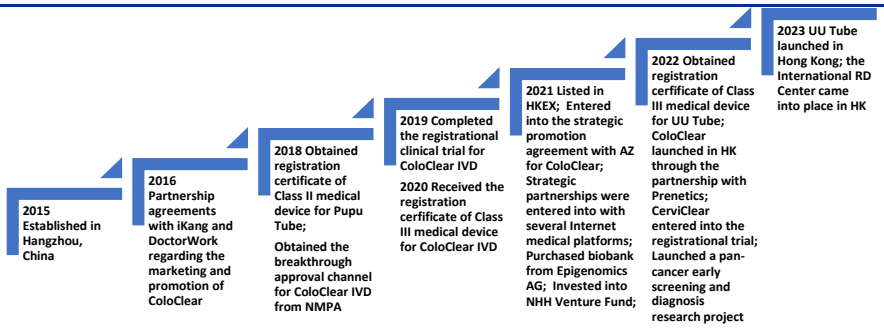
New Horizon Health (NH Health) is the first biotech company focusing on developing and commercializing cancer screening products in China. Currently, the company has three commercialized products (ColoClear, Pupu Tube and UU Tube), and other products or studies under development. The three commercialized products include ColoClear and Pupu Tube for colorectal cancer screening, as well as UU Tube for Helicobacter Pylori (Hp) screening. Besides, other products or studies under development include CerviClear for cervical cancer (CC), LiverClear for liver cancer screening, NPClear for nasopharyngeal cancer and a Pan-cancer Early Detection (PANDA) study in China, etc.

In November 2015, New Horizon Health was established in Hangzhou, China. In August and October 2016, the company entered into partnership agreements regarding marketing and promotion of ColoClear with iKang (physical examination center) and DoctorWork (online medical platform) respectively. In March 2018, the company obtained the registration certificate for Class II medical device for Pupu Tube. In November 2020, the company obtained the registration certificate for Class III medical device for ColorClear, which was NMPA's first registration certificate for early cancer screening products.

In February 2021, the company was listed on the Hong Kong Stock Exchange, becoming the first Hong Kong-listed company focusing on early cancer screening. In March 2021, the company and AstraZeneca entered into a three-year exclusive co-promotion agreement for the promotion of ColoClear in mainland China. Besides, the company also entered into strategic partnerships with several online medical platforms in 2021, including JD Health, PA Gooddoctor and Picahealth, etc. In August 2021, the company purchased a biobank from Epigenomics AG with total consideration of US$6.7m. In September 2021, the company invested in the NHH Venture Fund. In December 2021, the company signed an exclusive licensing agreement with Orbit Genomics regarding their technology in Greater China.

In January 2022, the company obtained the registration certificate for Class III medical device for UU Tube. In June 2022, ColoClear was launched in Hong Kong through a partnership with Prenetics. In November 2022, the company's urine-based screening product for cervical cancer, CerviClear, entered into the registrational trial. In November 2022, the company launched a Pan-cancer Early Detection (PANDA) study with Peking University Medical School. In January 2023, UU Tube was launched in Hong Kong through a partnership with Phase Scientific. In February 2023, the company's International R&D Center was launched in HongKong.

Figure 1: Company history



Source: Prospectus, NH's official website, NH's announcements, SWS Research

The company's commercialized products, ColoClear, Pupu Tube (for colorectal cancer screening) and UU Tube (for Hp screening), received the NMPA's approval in November 2020, March 2018 and January 2022 respectively, prices at Rmb1,996, Rmb99 and Rmb149 in China.

In terms of the products under development, CerviClear for cervical cancer screening has completed the first-patient-in in November 2022 and entered into the registrational trial officially. In addition, LiverClear for liver cancer screening is under the late stage of development before the registrational trial, and it is expected to initiate a prospective multi-centre clinical trial in 1Q23E. In addition, NPClear for nasopharyngeal cancer screening is under development in collaboration with Sun Yat-Sen University Cancer Center.

In November 2022, the company and Peking University Medical School jointly launched a Pan-cancer Early Detection (PANDA) study in China, which plans to cover early screening and diagnosis of over 20 types of high-risk cancers in China, including lung cancer, colorectal cancer, gastric cancer, liver cancer, cervical cancer and breast cancer etc., through the company's STAR-seq technology platform with independent intellectual property rights in the next six years.

Figure 2: New Horizon Health's pipeline

Product/ Study	Indication	Sample Type	Technology	NMPA Approval Time	NMPA Approval Type	Price (Rmb)	Development stage			
							Early Development	Late Development	Registrational Trial	NMPA Approval
ColoClear	Colorectal Cancer	Stool	FIT-DNA	Nov-20	Class III medical device	1,996				
Pupu Tube	Colorectal Cancer	Stool	FIT (colloidal gold)	Mar-18	Class II medical device	99				
UU Tube	Gastric Cancer	Stool	Immuno-based (emulsion process)	Jan-22	Class III medical device	149				
CerviClear	Cervical Cancer	Urine	qPCR	-	-	-				
LiverClear	Liver Cancer	Blood	Multi-omics	-	-	-				
NPClear	Nasopharyngeal Cancer	Nasal Swab	qPCR (DNA, RNA, protein)	-	-	-				
PANDA	Pan Cancer	Blood	Multi-omics	-	-	-				
Others	Undisclosed	Undisclosed	Multi-omics							

Source: NH's announcements, NH's official website, NH's JD self-operated flagship store, SWS Research

New Horizon Health has an experienced and professional management team with an international perspective. The CEO, Mr. Zhu Yeqing, has over 20 years of management experience, and held a number of positions including managing director at GE (China) Co., Ltd. The chairman of the Board and CSO, Dr. Chen Yiyou, has over 20 years of research and development experience in the field of oncology, and is the inventor of six patents in the US and over 20 patent applications globally.

The CTO, Dr. Lu Ning, has over 17 years of experience in molecular diagnostics and medical devices, and has over 10 years of IVD experience in multiple global companies like Roche Diagnostics and Quest Diagnostics, leading the development of eight IVD products. In June 2020, Mr. Gao Yu joined in the company and served as CFO. Mr. Gao has over 15 years of healthcare industry investing experience.

Figure 3: Experienced management team

Name	Position	Major responsibility	Year of joining the company	Summary
Mr. Zhu Yeqing	Co-founder, CEO and the chairman of the Board	Overall strategic planning, business direction, business sustainability and operational management	2015	Mr. Zhu Yeqing has over 20 years of management experience and currently served as a council member of the Cancer Foundation of China. From 1996 to 1999, Mr. Zhu worked as a sales manager at the Beijing office of Samsung Corporation. From 2000 to 2013, Mr. Zhu held a number of positions including managing director at GE (China) Co., Ltd. Mr. Zhu obtained the Bachelor's degree in Biochemistry at Peking University in July 1992, and obtained the Master's degree in Business Administration from Guanghua School of Management of Peking University in July 2001.

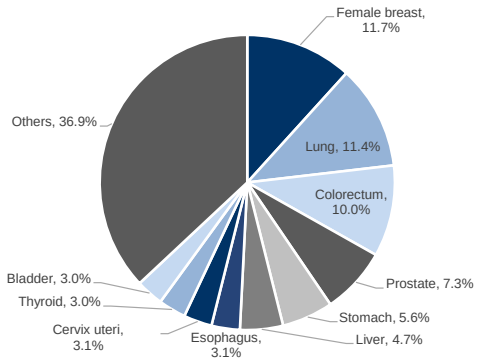
Dr. Chen Yiyou	Co-founder, executive director, and CSO	Overall research, technology and clinical development; participating in overall strategic planning and business direction	2015	Dr. Chen Yiyou has over 20 years of research and development experience in the field of oncology, and is the inventor of six patents in the US and over 20 patent applications globally. From 1998 to 2003, Dr. Chen served in various positions including drug discovery project leader at Genencor International Inc. From 2003 to 2006, Dr. Chen co-founded Starvax Inc. and served as CSO. In 2006, Dr. Chen co-founded Crown Bioscience Inc., and served as CSO from 2012. Since 2013, Dr. Chen has served as a board member of Med Data Quest, Inc. and a director at Beijing Percans Oncology Co., Ltd. In 2014, Dr. Chen co-founded Rejuven Dermaceutical Co., Ltd., where he served as a director and a supervisor until 2020. Since 2018, Dr. Chen has served as a director at Cothera Bioscience, Inc. Dr. Chen obtained the Bachelor's degree in Biochemistry from Peking University in July 1992, and the Doctoral degree in Experimental Pathology from the University of Utah in the US in July 1997.
Dr. Lu Ning	Co-founder and CTO	Development of cancer screening and testing technologies; focusing on clinical development and regulatory approval	2015	Dr. Lu Ning has over 17 years of experience in molecular diagnostics and medical devices, and has over 10 years of IVD experience in multiple global companies, leading the development of eight IVD products. From 2004 to 2007, Dr. Lu worked as a Senior Scientist in the RD department of Quest Diagnostics. From 2007, Dr. Lu served as a manager at Roche Diagnostics, developing IVD products for US and European markets. Dr. Lu is one of the inventors of two patents, namely "bordetella detection assay" and "HAV detection". Dr. Lu obtained the Bachelor's degree in Biochemistry in July 1992 from Peking University, and the Doctoral degree of Philosophy in September 1999 from Duke University in the US. Subsequently, Dr. Lu served as a postdoctoral researcher at the Department of Biological Sciences, Stanford University.
Mr. Gao Yu	CFO	Financial and strategic planning, business development; participating in operational management and investor relations activities	2020	As a private equity investor, an investment banker, and a management consultant, Mr. Gao Yu has over 15 years of healthcare industry investing experience. From 2007 and 2014, Mr. Gao served as a business consultant and various other roles at ZS Associates in New York. From 2014 to 2016, Mr. Gao was an investment banking associate at Bank of America Merrill Lynch in New York. From 2016, Mr. Gao was a vice-president at FountainVest Partners. Mr. Gao obtained the Bachelor's degree in Electrical Engineering from Shanghai Jiao Tong University in July 2005, the Master's degree in Science from Purdue University in the US in December 2006, and the MBA from Columbia Business School in the US in May 2014.

Source: Prospectus, NH's official website, NH's announcements, SWS Research

2. Overview of the cancer screening market

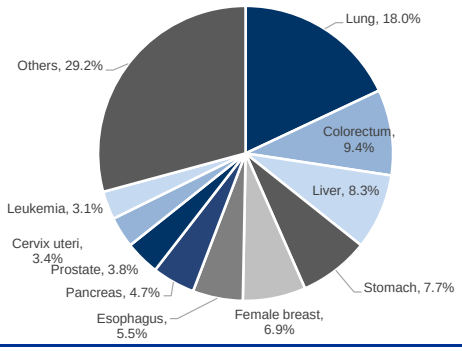
According to the global cancer statistics from the International Agency for Research on Cancer (IARC), the number of global new cancer cases and deaths stood at 19.29m and 9.96m in 2020, respectively. The top five cancer incidence by type were breast cancer, lung cancer, colorectum cancer, prostate cancer and gastric cancer, with new cancer cases of 2.26m, 2.21m, 1.93m, 1.41m and 1.09m, accounting for 11.7%, 11.4%, 10.0%, 7.3% and 5.6%, respectively, in 2020. Besides, the top five mortality by cancer type were lung cancer, colorectal cancer, liver cancer, gastric cancer and breast cancer, with deaths reaching 1.80m, 0.94m, 0.83m, 0.77m and 0.68m, representing 18.0%, 9.4%, 8.3%, 7.7% and 6.9% of the total number, respectively.

Figure 4: Distribution of global cancer incidence by cancer type (2020)



Source: IARC, SWS Research

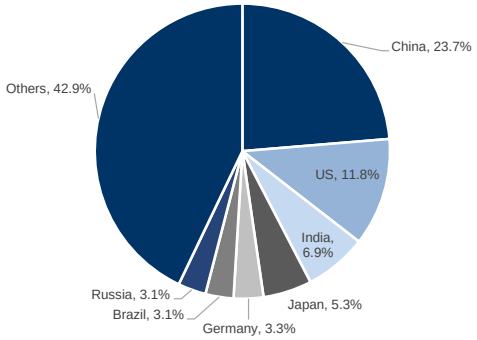
Figure 5: Distribution of global cancer mortality by cancer type (2020)



Source: IARC, SWS Research

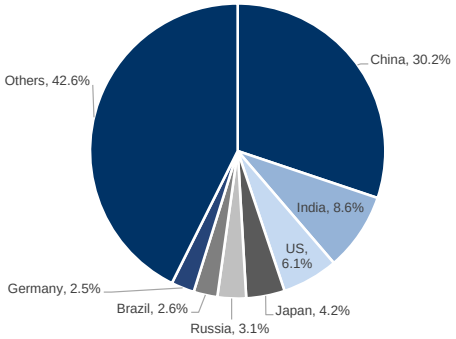
In 2020, both the number of new cancer cases and deaths in China ranked first globally, reaching 4.57m and 3.00m, respectively, accounting for 23.7% and 30.2%, much higher than other countries. In comparison, the number of new cancer cases and deaths in the US ranked second and third globally, standing at 2.28m and 0.61m, respectively, representing 11.8% and 6.1% of the total number.

Figure 6: Distribution of global cancer incidence by country (2020)



Source: IARC, SWS Research

Figure 7: Distribution of global cancer mortality by country (2020)



Source: IARC, SWS Research

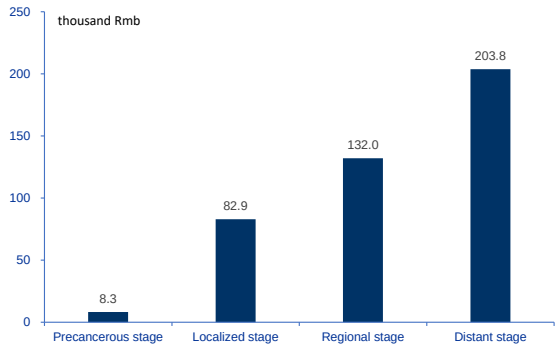
According to the National Cancer Institute (NCI), all cancers can be categorized into five development stages, which are precancerous stage, localized stage (early stage), regional stage, distant stage (advanced stage) and unknown stage. Early detection of cancer can effectively reduce the treatment cost. Taking the colorectal cancer treatment cost by stage in China as an example, if the cancer is detected at precancerous or early stage, the cost of treatment is only Rmb8,300 and Rmb82,900. If the cancer is progressed into regional or advanced stage, the cost of treatment will be increased to Rmb132,000 or Rmb203,800.

Figure 8: Different development stages of cancer

Stage	Summary
Precancerous stage	Abnormal cells are present but have not spread to nearby tissue, which are associated with an increasing risk of developing into cancer
Localized stage (Early stage)	The cancer is found only in certain part of the body
Regional stage	The cancer has spread to regional lymph nodes
Distant stage (Advanced stage)	The cancer is metastasized
Unknown stage	-

Source: Prospectus, NCI, SWS Research

Figure 9: Colorectal cancer treatment cost by stage in China (2019)



Source: Prospectus, SWS Research

Early detection of cancer can be achieved through various types of screening methods. Currently, early cancer screening includes traditional screening methods and liquid biopsy. Traditional screening methods are mainly divided into three types, which are imaging procedures, endoscopic screening and tumor marker screening. However, these methods have limitations, such as radioactive damage, lag, invasiveness and lack of sensitivity and specificity.

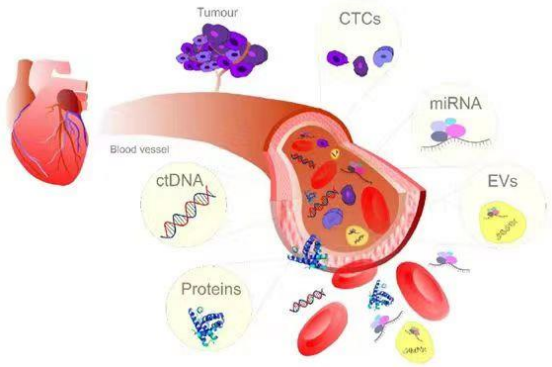
In recent years, liquid biopsy, a non-invasive screening method, can provide new ideas for early cancer screening with blood, urine, cerebrospinal fluid and ascites sampling, with advantages of non-invasive, comprehensive, real-time and accurate. Among which, blood biopsy is the main research direction, focusing on testing the circulating cell-free DNA (cfDNA), circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), microRNA (miRNA) and exosomes etc. Currently, liquid biopsy is still under early development stage.

Figure 10: Summary of traditional screening methods

Methods	Characteristics	Limitations
Imaging procedures	With the help of various imaging techniques, clear images are created for internal structures and organs to determine the status of physiological functions and pathological changes, and to determine whether cancer has occurred	Radioactive and lagging
Endoscopic screening	With the help of advanced optical instruments, the body is accessed from outside the body through natural channels to detect the occurrence of mutations	Limited medical resources; strong sense of discomfort; low compliance
Tumor marker screening	Specific substances, such as antigens, enzymes, receptors, hormones, specific proteins and other components that increase with the presence of a tumor can be rapidly detected by immunological and biological methods to further determine whether there exist tumor mutations	Lack of sensitivity and specificity

Source: Qianzhan, SWS Research

Figure 11: Biomarkers in liquid biopsy



Source: *Liquid Biopsy is Instrumental for 3PM Dimensional Solutions in Cancer Management*, SWS Research

Sensitivity and specificity are the main evaluation criteria for early cancer screening products. Specifically, sensitivity is also called "true positive rate", which is the probability of cancer in patients with positive test results. The specificity, also known as the "true negative rate," is the probability that patients with negative test results do not have cancer. In addition, other criteria include positive predictive rate (PPV) and negative predictive rate (NPV). PPV refers to the probability that a user with a positive test result is actually a cancer patient, which is a measure of the ability of early-screening products to avoid "misdiagnosis." NPV refers to the probability that a user with a negative test result is not a cancer patient, which measures the ability of early screening products to "miss" the test. A higher NPV means that the users can be more comfortable with the negative result.

Figure 12: Evaluation criteria for early cancer screening products

	Positive (P)	Negative (N)	
True (T)	True Positive (TP)	False Negative (FN)	
False (F)	False Positive (FP)	True Negative (TN)	
	P = TP + FP	N = FN + TN	

$$\text{Sensitivity} = \frac{TP}{TP + FN}$$

Higher sensitivity means the higher "true positive rate" and lower proability of "miss" the test.

$$\text{Specificity} = \frac{TN}{TN + FP}$$

Higher specificity means the higher "true negative rate" , reduce unnecessary follow-up tests for healthy people with positive test results.

$$\text{Positive predictive value (PPV)} = \frac{TP}{TP + FP}$$

Measure the ability of early-screening products to avoid "misdiagnosis."

$$\text{Negative predictive value (NPV)} = \frac{TN}{TN + FN}$$

Measure the ability of early screening products to "miss" the test.

Source: Prospectus, *Classification assessment methods*, SWS Research

At present, Exact Sciences and Epigenomics AG are the main overseas early cancer screening companies, among which, Cologuard from Exact Sciences and Epi proColon from Epigenomics AG received the FDA's approval for colorectal cancer screening in 2014 and 2016, using FIT-DNA and liquid biopsy technology for colorectal cancer screening. Besides, multiple overseas research on pan-cancer screening is ongoing, with liquid biopsy as the main technology.

Figure 13: Part of overseas early cancer screening products and clinical studies

Company	Product	Indication	R&D progress	Technology
Exact Sciences	**Cologuard**	**colorectal cancer**	**FDA approval (2014)**	**FIT-DNA (qPCR)**
	Oncoguard	liver cancer	under development	liquid biopsy
	CancerSEEK	pan cancer	under development	liquid biopsy (qPCR)
Epigenomics AG	**Epi proColon**	**colorectal cancer**	**FDA approval (2016)**	**liquid biopsy (blood test, qPCR)**
Freenome	PREEMPT CRC study	colorectal cancer	under development	liquid biopsy (NGS)
	Sanderson study	pan cancer	under development	liquid biopsy
GRAIL	Galleri	pan cancer	under development	liquid biopsy (NGS)
Guardant Health	ECLIPSE study	colorectal cancer	under development	liquid biopsy (NGS)
	SHIELD study	lung cancer	under development	liquid biopsy

	ALMANAC study	pan cancer (colorectal cancer, breast cancer, lung cancer)	under development	liquid biopsy
CellMax Life	FirstSight	colorectal cancer	under development	liquid biopsy

Source: Prospectus, companies' official websites, SWS Research

For the domestic market, ColoCear is the only product in China that received NMPA's approval for colorectal cancer screening. In terms of the Hp screening, UU Tube from NH Health and Kangjianyou from CoWin Biosciences obtained NMPA's approval in January and December 2022, respectively. Due to the large enrollment, retrospective clinical trials combined with prospective clinical trials and long follow-up periods of registrational clinical samples for early cancer screening products, companies with earlier clinical trials have first-mover advantages. Currently, NH Health, Genetron, Berry Oncology and BGI Genomics are conducting a number of clinical studies focusing on early cancer screening for liver cancer.

Figure 14: Part of domestic early cancer screening products and clinical studies

Company	Product	Indication	R&D progress	Technology
NH Health	**ColoClear**	**colorectal cancer**	**NMPA approval (November 2020)**	**FIT-DNA**
	Pupu Tube	**colorectal cancer**	**NMPA approval (March 2018)**	**FIT, colloidal gold**
	UU Tube	**gastric cancer**	**NMPA approval (January 2022)**	**immuno-based**
	CerviClear	cervical cancer	under development	qPCR
	LiverClear	liver cancer	under development	multi-omics
	NPClear	nasopharyngeal cancer	under development	qPCR
	PANDA	pan cancer	under development	multi-omics
CoWin Biosciences	Kangjianyou	gastric cancer	NMPA approval (December 2022)	qPCR
Burning Rock	THUNDER	pan cancer	under development	liquid biopsy (NGS)
Genetron	HCCscreen	liver caner	under development	liquid biopsy (NGS)
Berry Oncology	Quansining	pan cancer	under development	liquid biopsy
	Laisining	liver caner	under development	liquid biopsy
BGI Genomics	SeqHPV	cervical cancer	under development	HPV DNA
	Huachangkang	colorectal cancer	under development	FIT-DNA
	Huaganning	liver cancer	under development	liquid biopsy

Source: Prospectus, companies' official websites, SWS Research

In terms of policies related to early screening for cancer in China, to further increase the overall five-year survival rate of cancer and expand the coverage of early cancer diagnosis and treatment in China, authorities have introduced a number of policies since 2016. In September 2019, NHC released the *Healthy China Action – Cancer Prevention and Control Implementation Plan (2019-2022)*, which stated that by 2022, the overall five-year survival rate of cancer will be increased by 3% compared to 2015, and the coverage rate of key screening districts and counties with high-risks will reach over 80%. Besides, in April 2022, the State Council released *Highlights of the Program for Healthy China in 2022*, which stated to promote the construction of pilot cancer screening and early diagnosis and treatment centres at district and county levels.

Figure 15: Policies on early cancer screening

Date	Related authority	Policy	Summary
Apr-22	State Council	Highlights of Program for Healthy China in 2022	**Promote the construction of cancer screening and early diagnosis and treatment centers at district and county levels,** and summarize and promote the work mechanism and management model of opportunistic screening such as upper gastrointestinal cancer.

Oct-21	NHC	Action Plan for Quality Improvement in Oncology Care	Local health authorities are required to strengthen the design of the system, formulate and improve screening guidelines for suitable tumors, specify safe, effective and economical screening methods, and conduct extensive training and popularization of science.
Aug-20	Ministry of Science and Technology	RD and Application of Technologies for Early Screening and Diagnosis of Highly Prevalent Malignant Tumors	Aim to build a highly sensitive, specific and economical technology system for early detection of malignant tumors, with fully independent intellectual property rights for screening/early detection kits, targeting lung and gastrointestinal cancers that are highly prevalent in China.
Sep-19	NHC	Healthy China Action – Cancer Prevention and Control Implementation Plan (2019-2022)	- By 2022, the overall 5-year survival rate of cancer will increase by 3% compared to 2015, the coverage rate of key screening districts and counties in high-incidence areas will reach 80%+. - Develop guidelines for early diagnosis and treatment of main cancers.
Jun-19	NHC	Program for Healthy China 2030 (2019-2030)	- By 2022 and 2030, the overall 5-year survival rate of cancer will be more than 43.3% and 46.6%. - The early diagnosis rate of key cancer species in high incidence areas will reach 55% and above and continue to improve.
May-18	State Council	Program for Deepening the Reform and Open-up of the Pilot Free Trade Zone in China (Tianjin)	Explore the construction of a demonstration center for the application of genetic diagnosis technology to carry out applications for the prevention and treatment of major diseases such as birth defects and tumors.
Dec-17	NHC	Technical Specification for Microarray Gene Chips for Individualized Medical Testing	Identify gene microarray technology can detect tumor genetic markers much earlier and easier.
Mar-17	State Council	the 13th Five-year Plan for Promoting Basic Public Services	Increase the screening rate and early diagnosis and treatment of common diseases among women and expand the coverage of cervical and breast cancer screening programs for rural women.
Jan-17	State Council	China's Medium-to- Long Term Plan for the Prevention and Treatment of Chronic Diseases (2017-2025)	**- Implement early diagnosis and treatment of cancer to reduce the risk of high-risk groups.** **- Propose the overall 5-year survival rate of cancer as the main target for prevention and treatment, with a baseline overall 5-year survival rate of 30.9% and a 5% increase by 2020 and 10% by 2025.**
Dec-16	State Council	the 13th Five-year Plan for Poverty Alleviation	**- Strengthen tumor follow-up and registration.** **- Expand the coverage of cancer screening and early diagnosis and treatment, and fully implement the free screening program for rural women for "two cancers" in poor areas.**
Dec-16	State Council	the 13th Five-year Plan for Health and Wellness	Advance the use of gene chips and sequencing technologies in the diagnosis of genetic diseases, early cancer diagnosis and disease prevention detection.
Nov-16	Ministry of Industry and IT, Development and Reform Commission, Ministry of Science and Technology, NHC, NMPA	Guideline of Program for the development of the Pharmaceutical Industry	Support the development of new medical technologies such as gene sequencing, focusing on the development of high-throughput biochemical analyzers and single-molecule gene sequencers.
Oct-16	General Offices of the CPC Central Committee and The State Council	Outline of Program for "Healthy China 2030"	**- Strengthen the cancer screening and diagnosis of chronic diseases, carry out early diagnosis and early treatment for major cancers in high incidence areas, and promote the opportunistic screening of chronic diseases such as cancers.** **- By 2030, the overall 5-year survival rate of cancer will be increased by 15%.**

Source: Prospectus, State Council, NHC, SWS Research

2.1 Colorectal cancer – Clear precancerous stage

Colorectal cancer is a common malignant tumor in the gastrointestinal tract. The incidence and mortality rates of colorectal cancer in China rank in the second and first tier globally. According to the global cancer

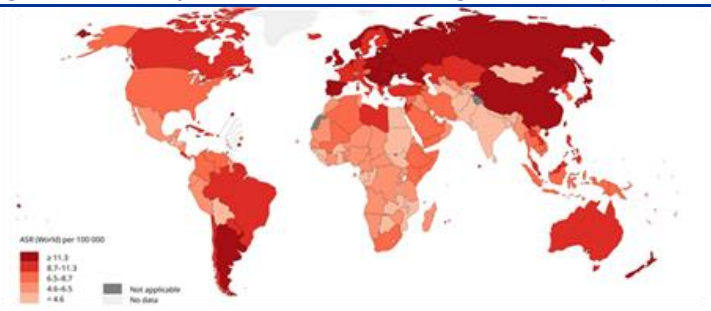
statistics from IARC, the age-standardised incidence and mortality rates of colorectal cancer in China were 239 and 120 per million people in 2020, respectively.

In comparison, the incidence and mortality rates of colorectal cancer in the US rank in the second and third tier globally, with the age-standardised incidence and mortality rates of 256 and 80 per million people in 2020, respectively. In terms of the mortality to incidence rate (a population-based indicator of survival rate), the number is 0.50 in China versus 0.31 in the US.

Figure 16: Incidence of colorectal cancer in the global market (2020)

Source: IARC, SWS Research

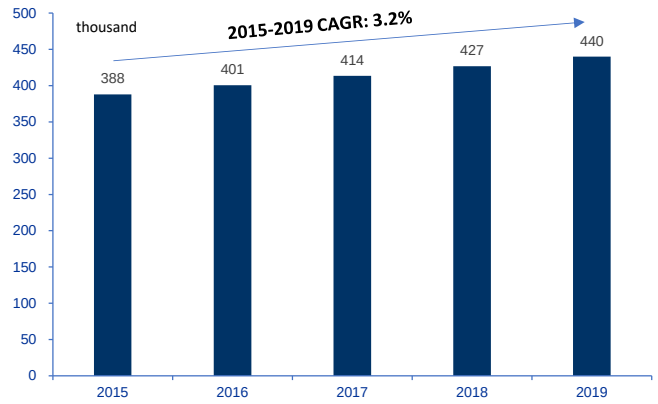
Figure 17: Mortality of colorectal cancer in the global market (2020)



Source: IARC, SWS Research

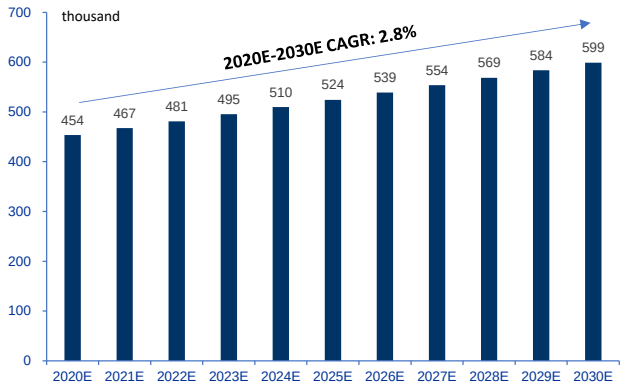
In terms of the number of new cases, colorectal cancer is the third most prevalent cancer in China, with rising diagnosed cases in recent years. According to Frost & Sullivan analysis, colorectal cancer incidence in China was 440,000 in 2019, with a Cagr of 3.2% from 2015 to 2019. It is expected the incidence of colorectal cancer in China to reach 480,000 in 2022. Due to the increasing awareness of colorectal cancer and the popularity of early cancer screening, colorectal cancer incidence in China is expected to reach c.600,000 in 2030, with a Cagr of 2.8% from 2020 to 2030.

Figure 18: Incidence of colorectal cancer in China (2015-2019)



Source: Frost & Sullivan analysis, SWS Research

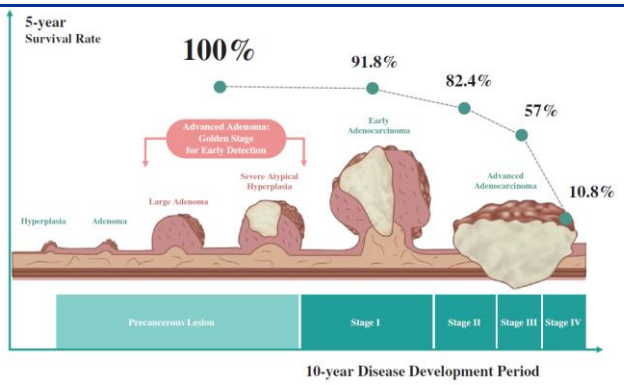
Figure 19: Mortality of colorectal cancer in China (2020E-2030E)



Source: Frost & Sullivan analysis, SWS Research

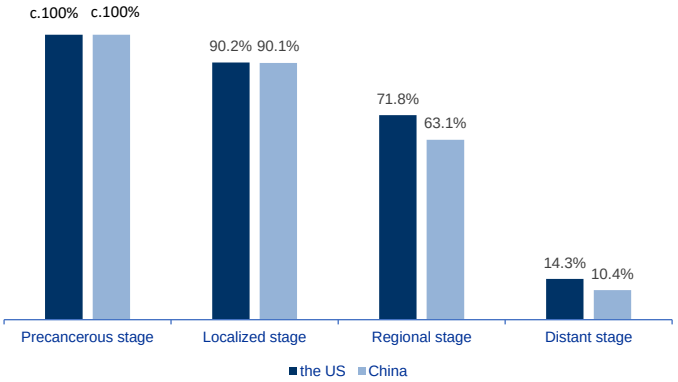
The development of colorectal cancer follows the sequence from adenoma to cancer. The progression from the precancerous stage to cancer generally takes five to ten years, with the advanced adenoma stage as the golden stage for early detection. In terms of the precancerous and localised stages of colorectal cancer, the five-year survival rate in the US and China are both c.100% and c.90%. The five-year survival rate declines significantly as the disease progresses to regional and distal stages. Thus, the rising awareness of early cancer screening will increase the five-year survival rate of colorectal cancer effectively.

Figure 20: Colorectal cancer development period and the five-year survival rate



Source: Prospectus, SWS Research

Figure 21: Five-year survival rate of colorectal cancer in the US and China

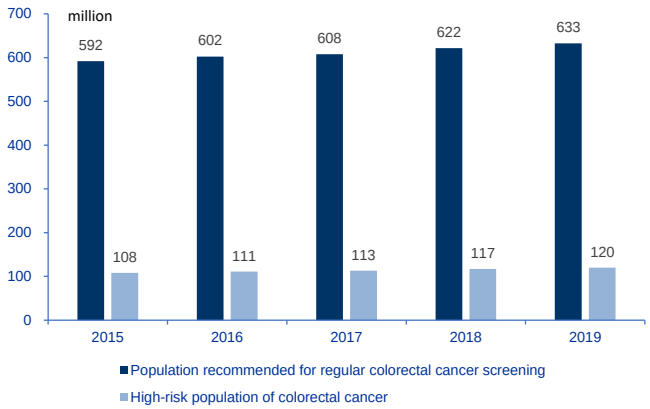


Source: Prospectus, SWS Research

Guidelines for Colorectal Cancer Screening and Early Diagnosis and Treatment in China (2020, Beijing) released by the National Cancer Center, recommends colorectal cancer screening for people aged between 40 and 75, considering the dietary habits and the decreasing average age of colorectal cancer cases in China.

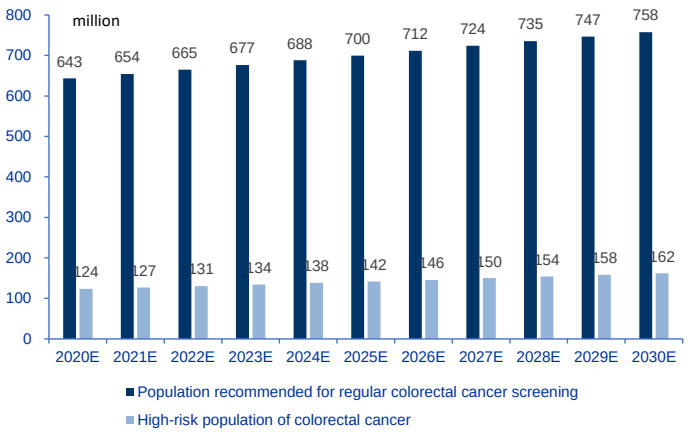
According to the Frost and Sullivan analysis, the population recommended for regular colorectal cancer screening in China was 633m in 2019, in which the high-risk population was 120m, accounting for c.20% of the total number. It is expected that the population recommended for regular colorectal cancer screening in China will reach c.130m in 2022E, with the high-risk population of 130m. Considering the increasing incidence of colorectal cancer in China, the population recommended for regular colorectal cancer screening in China is forecasted to reach c.760m in 2030E, with high-risk population to reach c.160m.

Figure 22: Population recommended for regular colorectal cancer screening in China (2015-2019)



Source: National Bureau of Statistics, Frost & Sullivan analysis, SWS Research

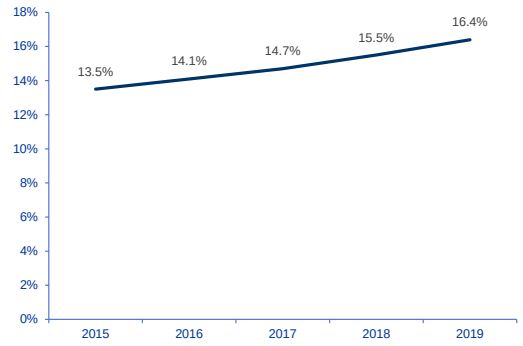
Figure 23: Population recommended for regular colorectal cancer screening in China (2020E-2030E)



Source: National Bureau of Statistics, Frost & Sullivan analysis, SWS Research

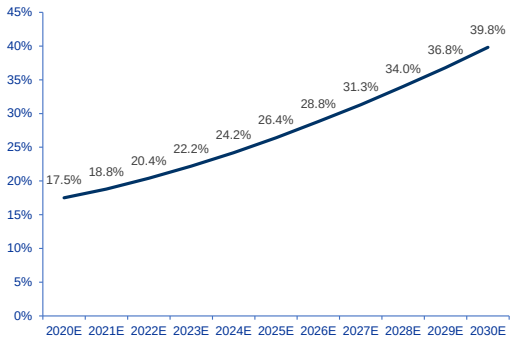
Now, early cancer screening is still in the early stage in China. According to the analysis of Frost and Sullivan, the penetration rate among the population recommended for colorectal cancer screening in China was only 16.4% in China, compared to 60.1% in the US. With rising cancer screening awareness in China and the support of relevant policies, the penetration rate in China is expected to reach 39.8% in 2030E.

Figure 24: Colorectal cancer screening penetration rate of recommended population in China (2015-2019)



Source: Frost & Sullivan analysis, SWS Research

Figure 25: Colorectal cancer screening penetration rate of recommended population in China (2020E-2030E)



Source: Frost & Sullivan analysis, SWS Research

Currently, colorectal cancer screening technologies include colonoscopy and stool-based tests. Colonoscopy is the gold standard for colorectal cancer diagnosis, but due to the invasiveness and inconvenience, as well as the lack of professional testing equipment and anesthetists in China, patient compliance for colonoscopy is relatively low. Besides, as blood in stool is the main symptom of colorectal cancer, stool-based tests are commonly used for cancer screening. Stool-based tests are mainly divided into FOBT/FIT and FIT-DNA. As a non-invasive and widely-used technology, patient compliance is relatively higher, but the sensitivity and specificity still need to be improved.

According to the latest *Guideline for the Treatment of Colorectal Cancer (2022)* released by CSCO, in terms of colorectal cancer screening in asymptomatic healthy people, colonoscopy and FIT are recommended as Class I and FIT-DNA is recommended as Class III for general risk groups. In addition, in January 2021, the *Guidelines for Colorectal Cancer Screening and Early Diagnosis and Treatment in China*, recommended FIT-DNA tests for colorectal cancer screening.

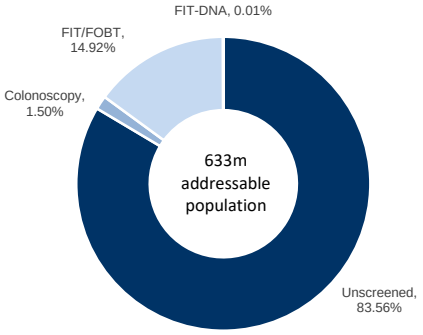
Figure 26: Comparsion of colorectal cancer screening technologies

	Imaging	Stool-based test		
	Colonoscopy (gold standard)	Fecal occult blood test (FOBT)	Fecal immunochemical test (FIT)	Multi-target stool-based DNA testing (FIT-DNA)
Introduction	Use a colonoscope to examine the rectum and the entire colon	Use a chemical to detect heme	Use antibodies to detect hemoglobin	Detect hemoglobin, along with certain DNA biomarkers
Advantage	- Visualization - Able to apply resection and biopsy - High sensitivity and specificity - Requires less frequent screening	- Non-invasive - Low price - Better compliance than colonoscopy		- Non-invasive - No dietary restrictions - Superior clinical performance (e.g. sensitivity, specificity, and PPV) than FOBT/FIT
Disadvantage	- Invasive and inconvenient - Lack of professional and anesthetists to operate in China - Not suitable for the specific population with other underlying diseases	- Low sensitivity - FOBT may require dietary restrictions - May require multiple tests		- Higher price than FOBT/FIT - 5 days turnaround time
Application scenario	- Hospital	- Hospital - Clinic - At-home		- Hospital - Clinic - At-home
Guidelines	Chinese Society of Clinical Oncology (CSCO) Colorectal Cancer Diagnosis and Treatment Guidelines 2022 (Class I recommendation)	-	Chinese Society of Clinical Oncology (CSCO) Colorectal Cancer Diagnosis and Treatment Guidelines 2022 (Class I recommendation)	Chinese Guidelines for Screening and Early Diagnosis and Treatment of Colorectal Cancer Expert Consensus on early Diagnosis and Screening Strategies for colorectal Tumors in China Expert Consensus on Early Diagnosis and Treatment of Colorectal Cancer in China Chinese Society of Clinical Oncology (CSCO) Colorectal Cancer Diagnosis and Treatment Guidelines 2022 (Class III recommendation)

Source: Prospectus, NCI, SWS Research

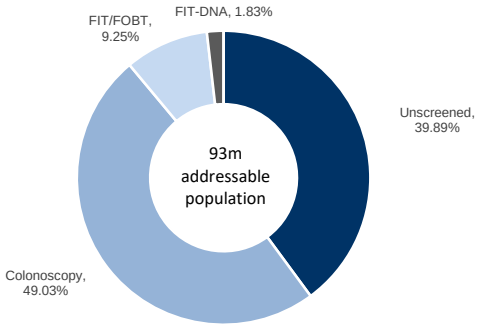
Colorectal cancer screening in China has large market potential in the future. For the 633m of the targeted colorectal cancer population in China in 2019, the penetration rate of colonoscopy, FIT/FOBT and FIT-DNA is only c.16%. The percentage of unscreened population reached 84%. In contrast, among the 93m of the targeted population in the US, the penetration rate of different screening technology methods is c.60%.

Figure 27: Penetration rate of different colorectal cancer screening technology in China (2019)



Source: Frost & Sullivan analysis, SWS Research

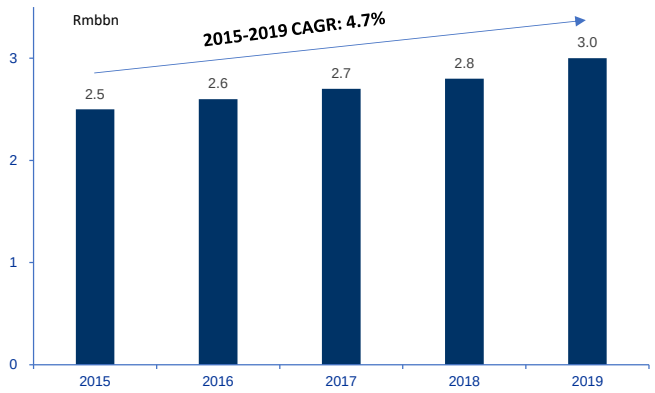
Figure 28: Penetration rate of different colorectal cancer screening technology in the US (2019)



Source: Frost & Sullivan analysis, SWS Research

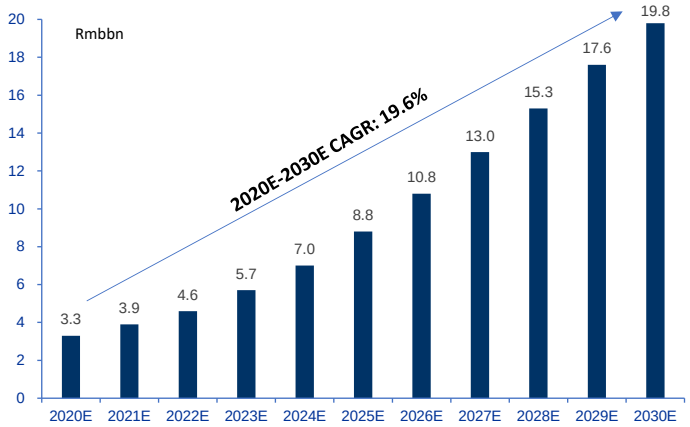
According to the Frost and Sullivan analysis, the colorectal cancer screening market in China was Rmb3.0bn in 2019 and Rmb4.6bn in 2022E. With increasing public awareness, government support and the improvement of early colorectal cancer screening technology, the colorectal cancer screening market in China is expected to reach Rmb19.8bn in 2030E, with a Cagr of 19.6% from 2020E to 2030E.

Figure 29: Market size of the colorectal cancer screening market in China (2015-2019)



Source: Frost & Sullivan analysis, SWS Research

Figure 30: Market size of the colorectal cancer screening market in China (2020E-2030E)



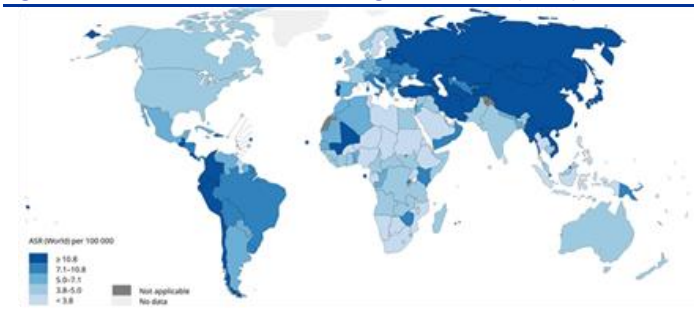
Source: Frost & Sullivan analysis, SWS Research

2.2 Gastric cancer – Hp is classified as Class I carcinogen

Gastric cancer originates in the most superficial mucosal epithelial cells of the stomach wall. Due to dietary habits and other reasons, gastric cancer is commonly seen in Asian countries like Mongolia, Japan, South Korea and China. According to the global cancer statistics from IARC, both the incidence and mortality rates of gastric cancer in China rank in the top tier globally, with an age-standardised incidence and mortality rate of 206 and 159 per million people. The age-standardised incidence of gastric cancer in Japan and South

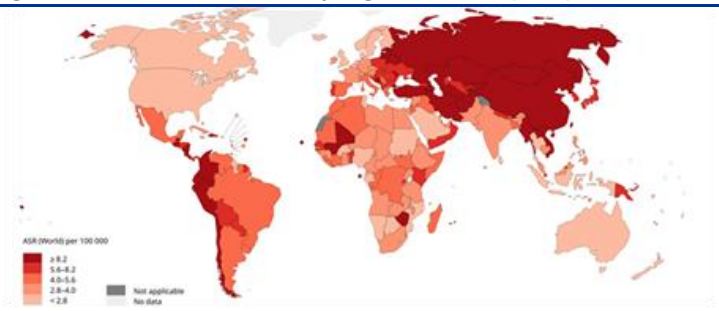
Korea are 316 and 279 per million people, which is higher than that of China, while the mortality rates are 82 and 61 per million people respectively, which is lower than that of China. This is mainly due to the more sufficient supply of gastroscopy in Japan and South Korea than in China, which reduces the mortality rate effectively by detecting gastric cancer earlier.

Figure 31: Global cancer incidence of gastric cancer (2020)



Source: IARC, SWS Research

Figure 32: Global cancer mortality of gastric cancer (2020)

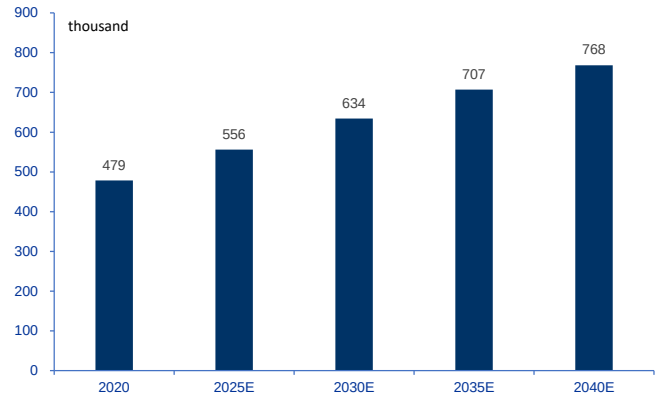


Source: IARC, SWS Research

According to the *2022 Version of Guidelines for Screening and Early Diagnosis and Treatment of Gastric Cancer in China*, gastric cancer is the fourth most prevalent cancer in China. According to the IARC, gastric cancer incidence in China was c.480,000 in 2020, and the number is expected to reach c.770,000 in 2040E, with the proportion of gastric cancer cases in China remaining stable at c.44%.

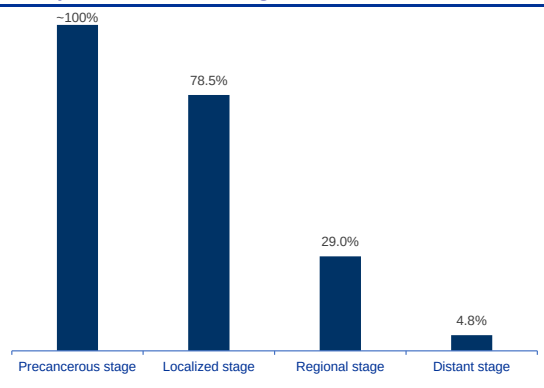
Early symptoms of gastric cancer are not obvious, with many patients at the middle or late stage when diagnosed. If the patient is in the precancerous and early stages, early screening for gastric cancer can increase the five-year survival rate effectively. According to the Frost and Sullivan analysis, the five-year survival rates of gastric cancer in the precancerous and localised stages are c.100% and 78.5%, while the five-year survival rates of gastric cancer in the regional and distant stages are only 29.0% and 4.8%.

Figure 33: Forecast of gastric cancer incidence in China (2020-2040E)



Source: IARC, SWS Research

Figure 34: Five-year survival rate of gastric cancer in China

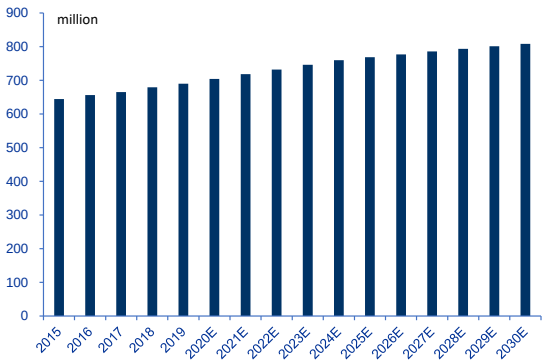


Source: Frost & Sullivan analysis, SWS Research

Guidelines for Gastric Cancer Screening and Early Diagnosis and Treatment in China (2022, Beijing) released by NCC recommends 45 as the starting age for gastric cancer screening, with screening ending at the age of 75 life expectancy of fewer than 5 years. According to the Frost and Sullivan analysis, the recommended population for gastric cancer screening was 690m in 2019, and the number is expected to reach 730m in

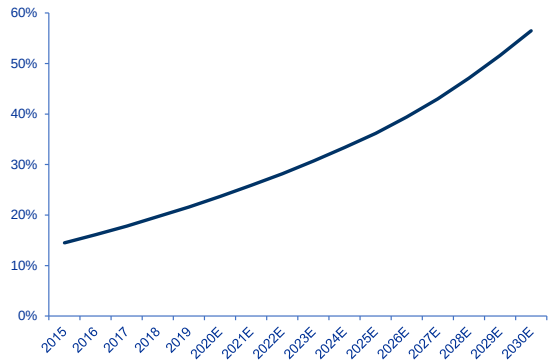
2022E and 810m in 2030E. Now, the penetration rate of recommended population for gastric cancer screening in China has increased from 14.5% in 2015 to 21.6% in 2019, which is expected to reach 28.2% in 2022E. With the update of cancer screening guidelines and the increasing public awareness towards early screening, the penetration rate is expected to reach 56.5% in 2030E.

Figure 35: Forecast of population recommended for gastric cancer screening in China (2015-2030E)



Source: Frost & Sullivan analysis, SWS Research

Figure 36: Forecast of gastric cancer screening penetration rate of recommended population in China (2015-2030E)

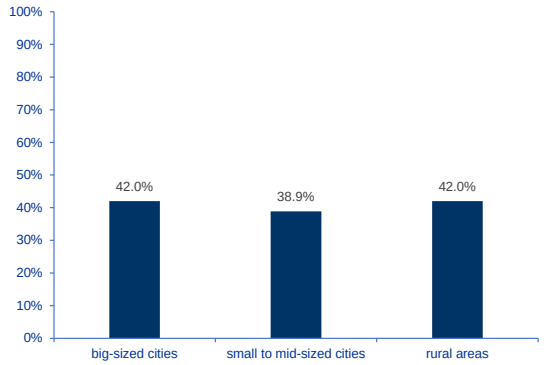


Source: Frost & Sullivan analysis, SWS Research

In 1994, Hp is classified as the Class I carcinogen of gastric cancer by WHO, and it has now been proven to be strongly associated with the progression of atrophic gastritis, gastric ulcers, gastric cancer and other related diseases. In 2019, Expert Consensus Opinions on Helicobacter pylori Prevention and Control of Gastric Cancer in China pointed out that Hp infection is the main cause of gastric cancer in China.

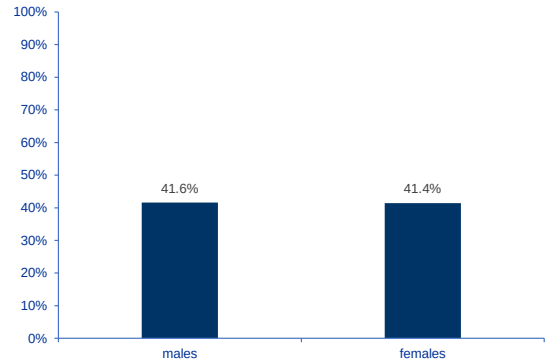
According to the Report on Nutrition and Chronic Diseases in China (2020), the overall Hp infection rate for residents aged from 18 to 64 years old is 41.5% in China. Specifically, the rate is 42.0% in big cities and rural areas, and the rate is 38.9% in small to mid-sized cities. Differentiated by gender, the rate is 41.6% for males and 41.4% for females.

Figure 37: Hp infection rate for residents aged from 18 to 64 years old in China by region



Source: Report on Nutrition and Chronic Diseases in China (2020), SWS Research

Figure 38: Hp infection rate for residents aged from 18 to 64 years old in China by gender



Source: Report on Nutrition and Chronic Diseases in China (2020), SWS Research

There are three main non-invasive Hp screening tests available in the market, including stool antigen test (SAT), serological test and urea breath test (UBT). UBT is the gold standard for Hp screening, but is exposed to radiation. In addition, as all Hp infections are antibody positive, antibody-based tests cannot distinguish

between the current and previous infections. Considering the cost and equipment, SAT is more suitable for large-scale screening than UBT and serological tests.

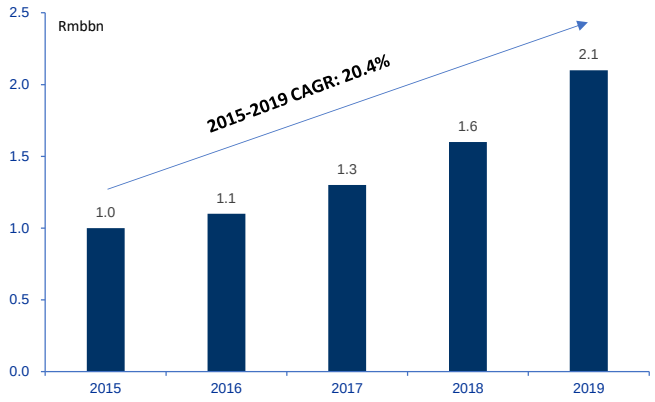
Figure 39: Hp tests for gastric cancer screening

	Urea breath test (UBT, gold standard)		Stool test	Serological test
	14C	13C	Stool antigen test (SAT)	Antibody-based test
Principle	When urease in Helicobacter pylori decomposes urea, carbon dioxide with carbon 13 or carbon 14 isotope label is produced. Measuring its content (carbon 13) or counting the flow rate (carbon 14) can reflect the number of bacteria of H. pylori in the body. If it exceeds a certain range, the positive result will be indicated		According to different detection principles, fecal antigen tests can be divided into enzyme-linked immunoassay and immunochromatography, and monoclonal method and polyclonal method according to different antibodies used	Two anti-HP antibodies can appear in the blood circulation of patients infected with Hp
Advantage	- Non-invasive - Highly accurate and reproducible - Less expensive than 13C	- Non-invasive - Highly accurate and reproducible - Free of radiation	- Non-invasive - More reliable than immunochromatography assay - Low price - Fewer needs for equipment than UBT	- Non-invasive - Accuracy is not affected by ulcer bleeding, gastric atrophy as well as the use of proton pump inhibitors or antibiotics - Less false-negative results
Disadvantage	- Influenced by many factors - Exposure to radiation, though the radiation is relatively low - Not suitable for women who are pregnant or breast breeding	- Influenced by many factors - Higher price than 14C - More needs for equipment than 14C	- Influenced by many factors - Influenced by preservation of the specimen	- Higher price than SAT or UBT - Longer duration to give test results - Cannot distinguish between current and previous infections

Source: Prospectus, Guidelines for Gastric Cancer Screening and Early Diagnosis and Treatment in China (2022, Beijing), SWS Research

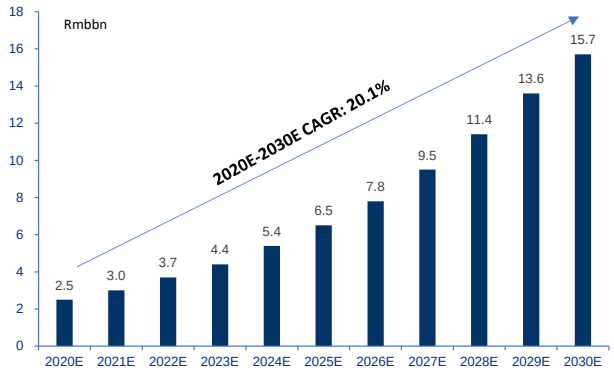
According to the Frost and Sullivan analysis, the market size of the gastric cancer screening market in China was c.Rmb2.1bn in 2019, with a Cagr of 20.4% from 2015 to 2019, which is expected to reach Rmb3.7bn in 2022E. With government support and increasing public awareness towards Hp, the gastric cancer screening market in China is expected to reach Rmb15.7bn in 2030E, with a Cagr of c.20.2% from 2020E to 2030E.

Figure 40: Gastric cancer screening market in China (2015-2019)



Source: Frost & Sullivan analysis, SWS Research

Figure 41: Gastric cancer screening market in China (2020E-2030E)

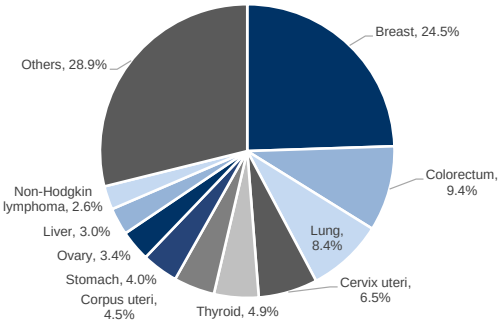


Source: Frost & Sullivan analysis, SWS Research

2.3 Cervical cancer – second largest female cancer

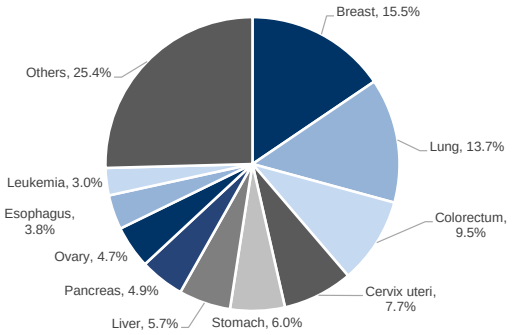
Cervical cancer is one of the most common female cancers. According to the global cancer statistics from IARC, cervical cancer was the fourth most prevalent female cancer globally in 2020, accounting for 6.5% of total incidence, following breast cancer (24.5%), colorectal cancer (9.4%) and lung cancer (8.4%). At the same time, cervical cancer was the fourth main cause of female cancer deaths, representing 7.7% of total deaths, following breast cancer (15.5%), colorectal cancer (13.7%) and lung cancer (9.5%).

Figure 42: Distribution of global cancer incidence by cancer type (female, 2020)



Source: IARC, SWS Research

Figure 43: Distribution of global cancer mortality by cancer type (female, 2020)

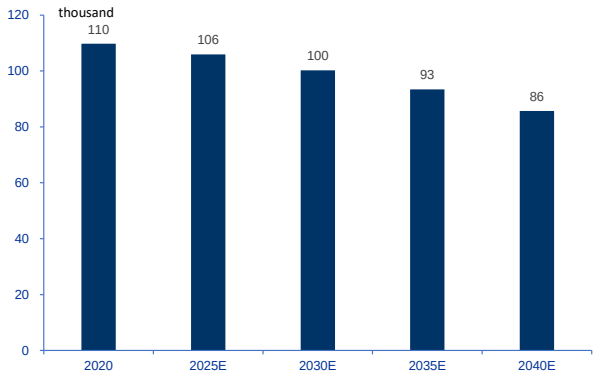


Source: IARC, SWS Research

According to *the National Cancer Center Annual Work Report in 2022* released by the NCC, cervical cancer is the sixth most prevalent female cancer in China. According to the IARC, cervical cancer incidence in China was c.110,000 in 2020E, accounting for c.18% of the total cervical cancer cases globally. Since 2009, China has launched a screening program for two cancers (breast cancer and cervical cancer) among rural women, which has been included in a major national public health service program. With the further support and implementation of policies, as well as the rising use of HPV vaccines, it is expected that the number of cervical cancer cases in China will decrease to c.85,000 in 2040E.

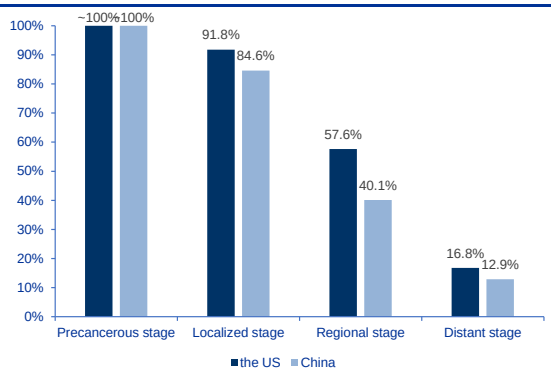
If there exists a precancerous cervical lesion (cervical intraepithelial neoplasia (CIN)) in cervix uteri, it has potential to develop into squamous cell carcinoma or adenocarcinoma within 10 to 15 years if untreated, which provides the time window for early cancer screening. According to data from Frost and Sullivan, detection of cervical cancer at the precancerous and early stage can increase the five-year survival rate effectively.

Figure 44: Forecast of cervical cancer incidence in China (2020-2040E)



Source: IARC, SWS Research

Figure 45: Five-year survival rate of cervical cancer in the US and China

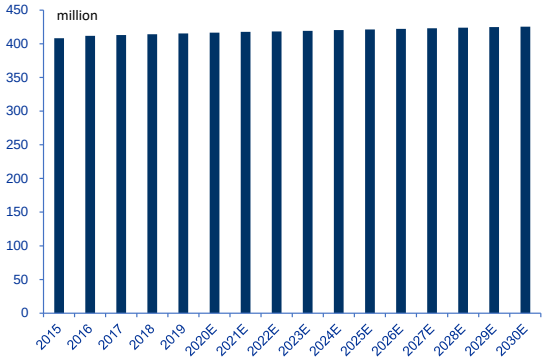


Source: Frost & Sullivan analysis, SWS Research

The Chinese Preventive Medicine Association (CPMA) recommends women aged between 25 to 65 years old to take cervical cancer screening. According to Frost and Sullivan analysis, the population recommended for cervical cancer screening in China was 420m in 2022E, and is expected to increase to 430m in 2030E. The main problem for cervical cancer screening in China is the lack of coverage, with the cervical cancer screening penetration rate of recommended population in China of only 51% in 2022. With the further

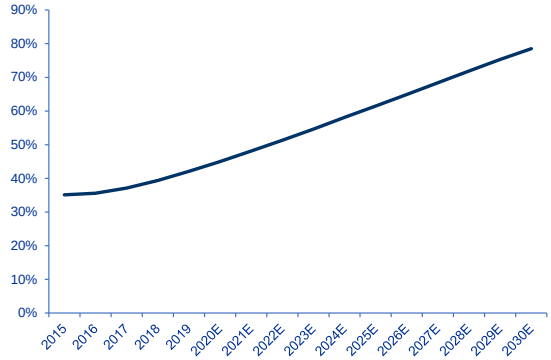
promotion of “two cancers” screening and the standardisation of screening and treatment, it is expected that the cervical cancer screening penetration rate of recommended population in China will increase significantly to 79% in 2030E.

Figure 46: Population recommended for cervical cancer screening in China (2015-2030E)



Source: Frost & Sullivan analysis, SWS Research

Figure 47: Cervical cancer screening peneration rate of recommended population in China (2015-2030E)



Source: Frost & Sullivan analysis, SWS Research

At present, cervical cancer screening technologies can be divided into molecular testing, cytology and visual inspection, in which pap smear is the gold standard, but with disadvantages of invasiveness and lack of privacy. The new version of the WHO guideline clearly suggests using HPV DNA as the primary cancer screening method, in which HPV 16 and HPV 18 can screen out the most high-risk group and have higher sensitivity and NPV, compared to other screening methods. Besides, molecular testing like DNA methylation and protein biomarkers are still in the development stage.

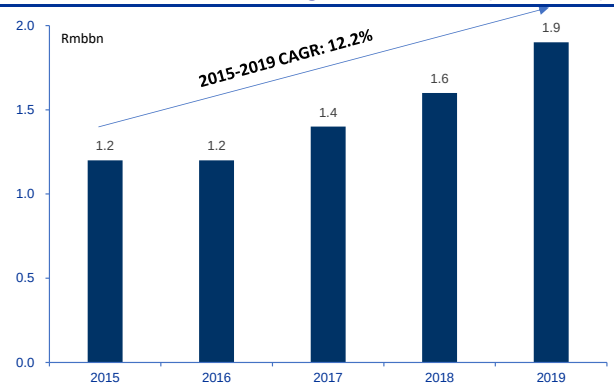
Figure 48: Summary of cervical cancer screening technologies

Screening method	Molecular testing	Cytology	Visual inspection
Available	**Nucleic acid amplification tests** - hrHPV DNA - HPV mRNA	**Pap smear (gold standard)** **Liquid-based cytology** **Dual staining to identify p16 and Ki-67**	Visual inspection with acetic acid or with Lugol's iodine
Under development	**DNA methylation** **Protein biomarkers** - HPV antibodies - Oncoproteins	-	AI

Source: WHO, SWS Research

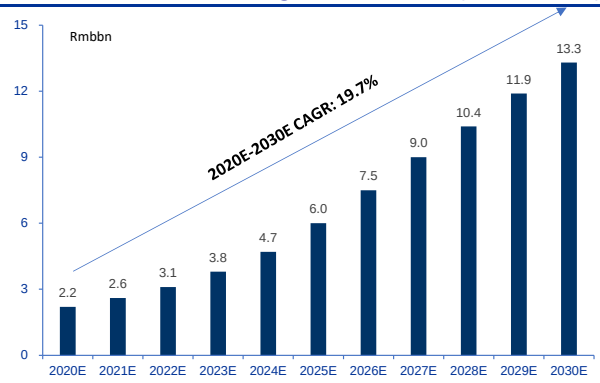
With the increasing penetration rate of “two cancers” screening, especially the government support for women in rural areas, and the increasing public awareness of HPV, the cervical cancer screening market in China still has large potential. According to Frost and Sullivan analysis, the market size of the cervical cancer screening market in China was Rmb1.9bn in 2019, with a Cagr of 12.2% from 2015 to 2019. The market is expected to reach Rmb3.1bn in 2022E and Rmb13.3bn in 2030E, with a Cagr of 19.7% from 2020E to 2030E.

Figure 49: Cervical cancer screening market in China (2015-2019)



Source: Frost & Sullivan analysis, SWS Research

Figure 50: Cervical cancer screening market in China (2020E-2030E)

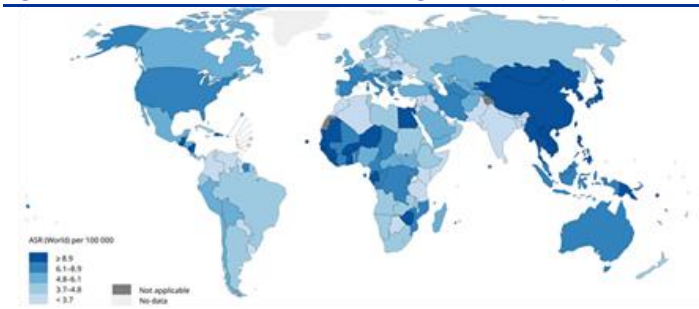


Source: Frost & Sullivan analysis, SWS Research

2.4 Liver cancer – cancer screening products in early development stage

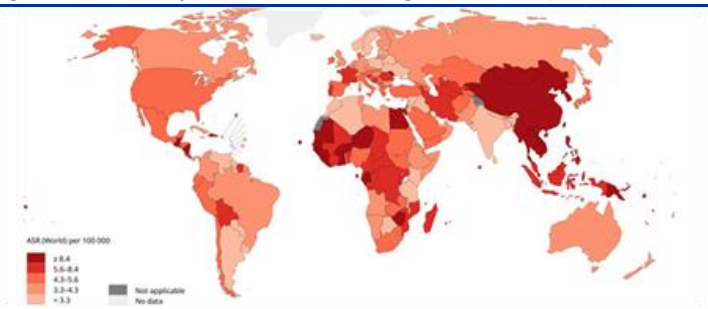
Liver cancer can be divided into primary and secondary liver cancers, and primary liver cancer is highly prevalent in China. According to the global cancer statistics from IARC, both the age-standardised incidence and mortality rate of liver cancer in China ranked in the top tier globally, which was 182 and 172 per million people in 2020 respectively. Risk factors for liver cancer mainly include hepatitis B virus (HBV), hepatitis C virus (HCV), alcohol and aflatoxin, etc., and liver cancer caused by alcohol increases at the highest rate.

Figure 51: Incidence of liver cancer in the global market (2020)



Source: IARC, SWS Research

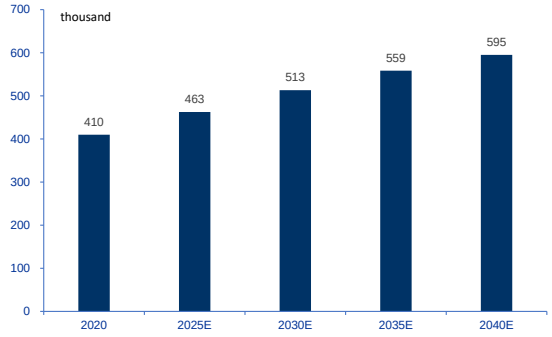
Figure 52: Mortality of liver cancer in the global market (2020)



Source: IARC, SWS Research

According to the IARC, the incidence of liver cancer in China was c.410,000 in 2020, accounting for 45% of the total liver cancer cases globally. The incidence is expected to reach 460,000 in 2025E and 510,000 in 2030E. The early symptoms of primary liver cancer are non-specific, while there are more symptoms in the middle and advanced stages. At present, the effectiveness of liver cancer screening in reducing mortality rate is still debatable, and the coverage rate of liver cancer screening in China is relatively low.

Figure 53: Incidence of liver cancer in China (2020-2040E)



Source: IARC, SWS Research

According to *the Guidelines for Liver Cancer Screening and Early Diagnosis and Treatment in China (2022, Beijing)*, only high-risk populations aged between 40 and 74 are recommended for liver cancer monitoring, and there is no screening strategy for the overall population. Currently, abdominal ultrasound combined with alpha-fetoprotein testing (AFP) is the most widely used technology for initial liver cancer screening, while CT and nuclear magnetic resonance are preferred for those who have abnormal results. Other screening methods include novel molecular markers, such as serum marker DCP(PIVKA-I), HBV mutation, ctDNA tumor-associated methylation, and non-coding RNA.

Figure 54: Summary of liver cancer screening technologies

<table>
<tr><th></th><th>Alpha-fetoprotein testing</th><th>Abdominal ultrasound</th><th>CT</th><th>Nuclear magnetic resonance</th><th>Serum protein markers</th><th>Novel molecular markers</th></tr>
<tr><td>Sensitivity and specificity</td><td>- Sensitivity: 39-65%
- Specificity: 76-94%</td><td>- Sensitivity for all stages: 84%
- Sensitivity for early stage: only 47%</td><td>- Sensitivity: 60-75%
- Specificity: 90%</td><td>- Sensitivity: 87%
- Specificity: 94%</td><td rowspan="3">DCP (PIVKA - I), has higher sensitivity, specificity and NPV compared to traditional AFP tests. Approved as validated marker for HCC in some countries such as Japan, Korea and India.</td><td rowspan="3">HBV mutations, ctDNA tumour-associated methylation, non-coding RNA, etc.</td></tr>
<tr><td>Advantage</td><td colspan="2">Mature; cheap; technical requirements for equipment is low; easy to implement in areas with different medical conditions</td><td>High resolution</td><td>High soft tissue resolution</td></tr>
<tr><td>Disadvantage</td><td>Limited sensitivity for early cancer screening</td><td>- Limited sensitivity for early cancer screening
- Easily affected by the operators' skills and experience, as well as obesity of clients</td><td colspan="2">High equipment price, which is difficult to promote as a primary screening technique</td></tr>
</table>

Source: *Guidelines for Liver Cancer Screening and Early Diagnosis and Treatment in China (2022, Beijing),* SWS Research

3. New Horizon Health – leading player in China's early cancer screening market

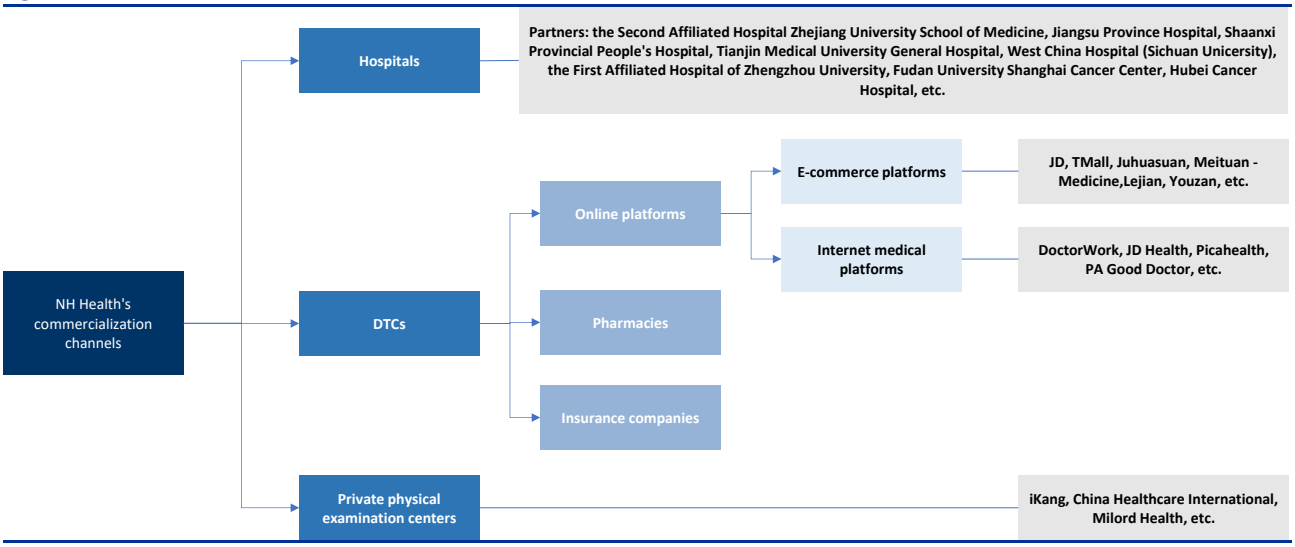
3.1 Sales ramp-up of commercialised products

The company started the commercialisation of products in 2018. Its commercialisation channels mainly include hospitals, DTCs (including e-commerce platforms, internet medical platforms, pharmacies and insurance companies) and private medical examination centres. After ColoClear obtained the NMPA's Class III medical device in November 2020, the company's main channel is gradually shifting from private physical examination centres with lower prices to hospitals with higher prices.

In terms of revenue mix of different sales channels, the hospital channel has become ColoClear's largest revenue contributor, with the fastest growth rate, followed by the DTC and private medical examination centres.

In March 2021, the company entered into a three-year strategic collaboration agreement with AstraZeneca, during which ColoClear will be the only colorectal cancer test for AstraZeneca to be promoted in the Chinese mainland. The company and AstraZeneca will jointly promote ColoClear in public hospitals, pharmacies and Internet hospitals in China.

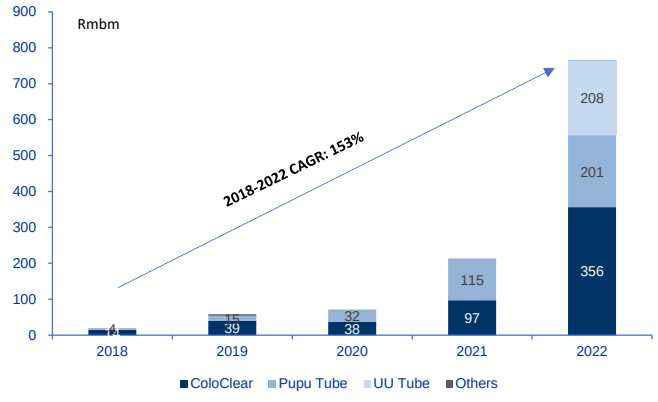
Figure 55: Diversified commercialisation channels of NH Health



Source: Prospectus, NH's announcements, NH's official website, SWS Research

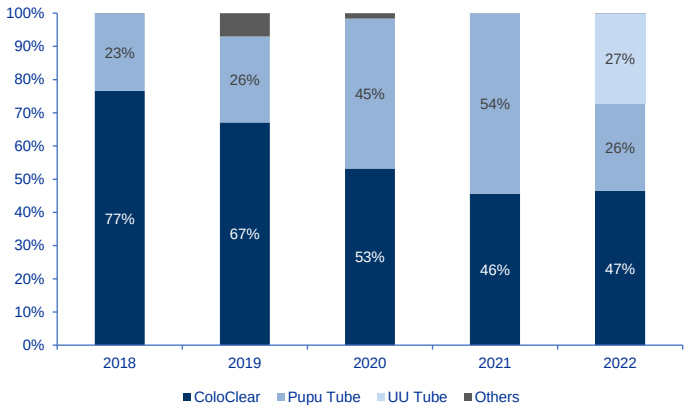
With the channel optimisation and sales ramp-up, the company's revenue increases rapidly. In 2022, sales of ColoClear, Pupu Tube and UU Tube reached Rmb360m (+266% YoY), Rmb200m (+74% YoY) and Rmb210m respectively, accounting for 47%, 26% and 27% of total revenue. From 2018 to 2021, the company's revenue grew at a Cagr of 153%.

Figure 56: Revenue growth by product (2018-2022)



Source: Prospectus, NH's announcements, SWS Research

Figure 57: Revenue mix by product (2018-2022)

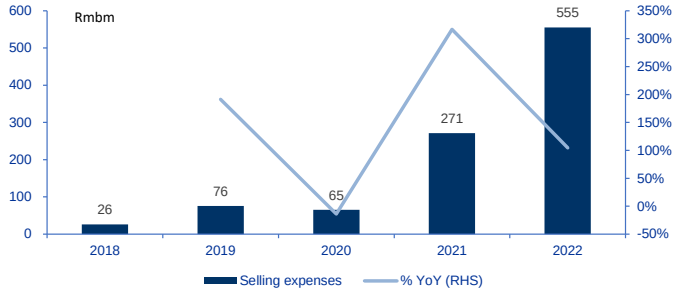


Source: Prospectus, NH's announcements, SWS Research

To further improve the sales channels, the company expands its clinical sales team gradually. Currently, the number of the company's sales and marketing staff has increased from 118 in 2020 to over 450 in 2022. Besides, the company continues to invest in marketing and promoting, and focuses on developing the

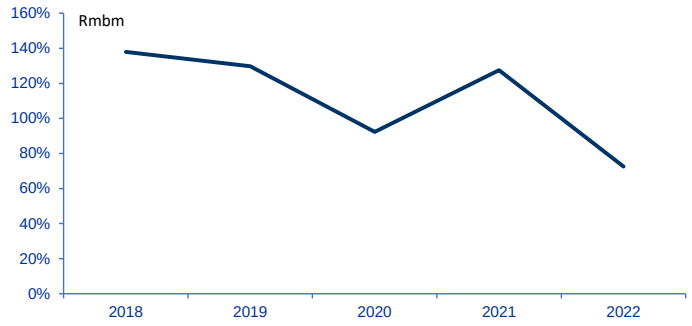
awareness of early screening among physicians and patients at the same time. In 2022, the company's selling expense reached Rmb555m (+105% YoY), with the selling expense ratio decreasing from 128% in 2021 to 73% in 2022.

Figure 58: Selling expenses (2018-2022)



Source: Prospectus, NH's announcements, SWS Research

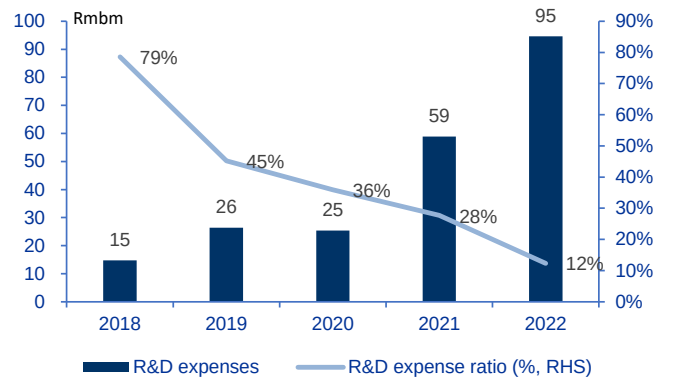
Figure 59: Selling expense ratio (2018-2022)



Source: Prospectus, NH's announcements, SWS Research

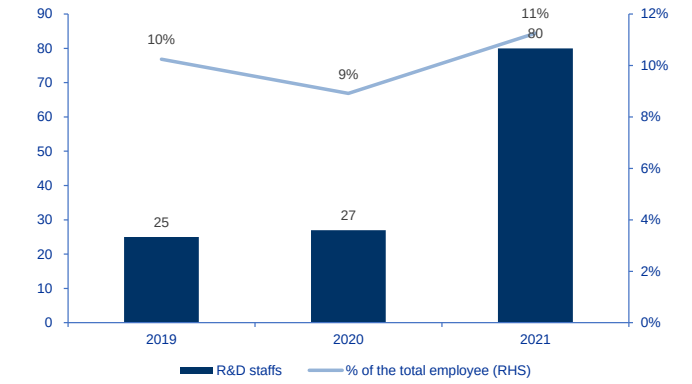
With CerviClear and LiverClear entering clinical trials, the company increased its R&D expenses from 2021. In 2022, the company's R&D expense was Rmb95m (+61% YoY). In addition, the number of its R&D staff increased from 27 in 2020 to 80 in 2021, accounting for c.11% of total employees.

Figure 60: R&D expenses (2018-2022)



Source: Prospectus, NH's announcements, SWS Research

Figure 61: Number of R&D staff (2018-2022)



Source: 21A ESG report of NH, SWS Research

At present, the company operates laboratory testing facilities in Beijing, Hangzhou and Guangzhou, with a total testing capacity of 2,000,000 tests per year. In addition, ColoClear and CerviClear can share the same PCR laboratory testing facilities, which can further improve its testing capability. Besides, the company's major manufacturing facilities are mainly located in the headquarters, Hangzhou, with the capacity of ColoClear of 5m, Pupu Tube of 10m and UU Tube of 10m. In addition, the company completed the issue of new shares of HK$780m in January 2023, with 40% of funds to be used for future capacity expansion.

Figure 62: Capacitiy of NH Health

Type	Location	GFA (㎡)	Testing capacity (tests per year)	Production capacity
Laboratory	Beijing	2,000	2,000,000	-
	Hangzhou	3,700		
	Guangzhou	1,300		
Production	Hangzhou	-	-	5m ColoClear 10m Pupu Tube 10m UU Tube

Source: Prospectus, NH's announcements, SWS Research

3.2 First-mover advantage

3.2.1 ColoClear – aimed at high-risk colorectal cancer population

ColoClear is the company's self-developed non-invasive stool-based FIT-DNA test, and is the first and only cancer screening product for colorectal cancer approved by the NMPA, aimed at high-risk colorectal cancer population. As an effective complement to colonoscopy, ColoClear aims to provide solutions for those high-risk populations who are unable or unwilling to take colonoscopy screening because of their underlying diseases.

ColoClear mainly includes four components, namely ColoClear IVD, risk assessment algorithm, sample collection kit and DNA extraction and purification technologies. In November 2020, ColoClear obtained the IVD registration certificate from the NMPA. Since 2015, the company has built a professional database of Asian-specific colorectal cancer methylation profiles, with over 100,000 clinical samples.

Figure 63: ColoClear's product design

Source: NH's JD self-operated flagship store, SWS Research

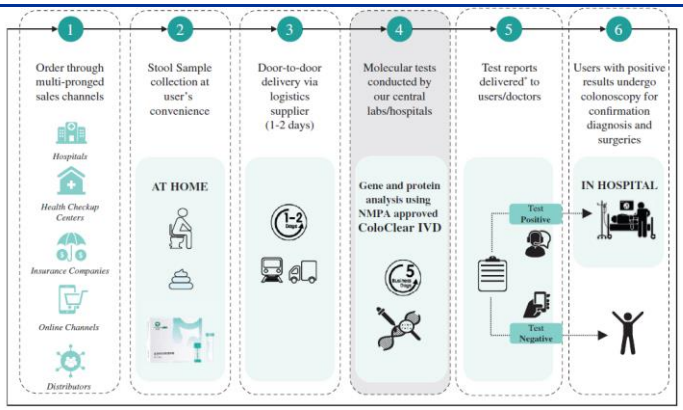
Figure 64: Components of ColoClear

Component	Type of registration	Time of NMPA's approval
ColoClear IVD	Class III medical device	Nov-20
Risk assessment algorithm	Class II medical device	Nov-20
Sample collection kit	Class I medical device	Dec-16
DNA extraction and purification technologies	Class I medical device	Aug-20

Source: Prospectus, SWS Research

Users can purchase ColoClear for testing at home from multiple channels. The testing process is easy and convenient, which takes a few minutes. After collecting the sample, the company's logistic partners (SF Express and JD Express) will collect the sample as required and deliver it to the nearest laboratory for testing within a few days. Generally, the company will send the test report within five working days after receiving the sample. If the user purchases ColoClear from hospital and tests positive, the user can get free colonoscopy screening service for once.

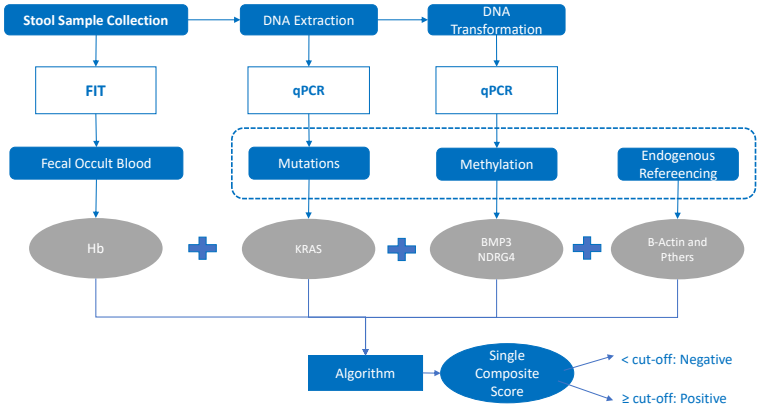
Figure 65: Testing process of ColoClear



Source: NH's 1H22 presentation, SWS Research

After receiving the sample, the company uses FIT-DNA testing methodology in the laboratory, which can detect the presence of KRAS gene mutations, BMP3/NDRG4 gene methylation and hemoglobin. The company's unique risk assessment algorithm is the first and only cancer screening method in China that combines all four parameters, which has gone through a large-scale prospective clinical trial.

Figure 66: ColoClear's testing technology



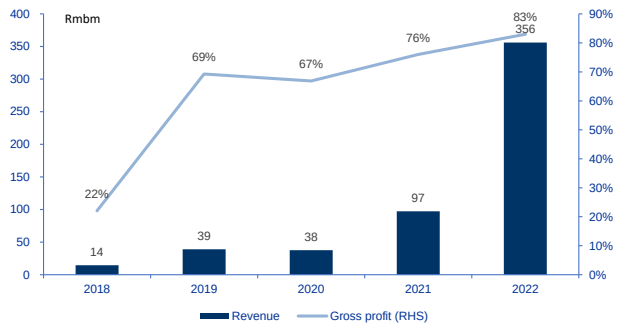
Source: Prospectus, ColoClear's technical review report, SWS Research

Since ColoClear received the IVD approval from the NPMA in November 2020, the sales source of ColoClear has switched from laboratory development testing (LDT) services to in vitro diagnostic (IVD) services. After receiving the price approval from provincial healthcare security admissions and being admitted to hospitals, we expect ColoClear's sales to ramp up. Sales of ColoClear reached Rmb360m (+266% YoY) in 2022. In 2022, the hospital channel became ColoClear's largest revenue contribution, with the fastest growth rate, followed by the DTC and private medical examination centres.

Due to the channel optimisation and economy of scale, the gross profit margin of ColoClear increased from 76% in 2021 to 83% in 2022. Besides, the shipment volume and revenue-recognising volume of ColoClear were 806,000 units (+21% YoY) and 361,000 units (+150% YoY) in 1H22, respectively.

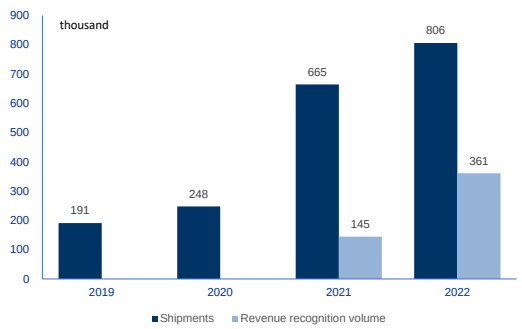
In May 2022, the company entered into a strategic partnership with Prenetics. Subsequently, ColoClear was launched in Hong Kong successfully in June, with a price of HK$3,000. As of end-September 2022, the sales volume of ColoClear reached 6,000 units in Hong Kong, of which more than 2,000 units were tested, mainly through private medical examination centres, such as EC Healthcare and Gleneagles Hospital, as well as insurance companies like MediFast. In 2022, sales of ColoClear reached c.Rmb0.6m in Hong Kong.

Figure 67: ColoClear's revenue and gross profit (2018-2022)



Source: Prospectus, NH's announcements, SWS Research

Figure 68: ColoClear's shipment volume and revenue-recognising volume (2019-2022)



Source: NH's 1H22 presentation, NH's announcements, SWS Research

Currently, there are four colorectal cancer screening products launched in the market from three companies, mainly focusing on stool-based tests. Among them, Cologuard from Exact Sciences (approve by the FDA in August 2014) and ColoClear from NH Health (approved by the NMPA in November 2020) are based on stool samples, which have advantages compared to Epi proColon from Epigenomics AG, approved by the FDA in April 2016 and based on blood tests, in terms of sensitivity and specificity.

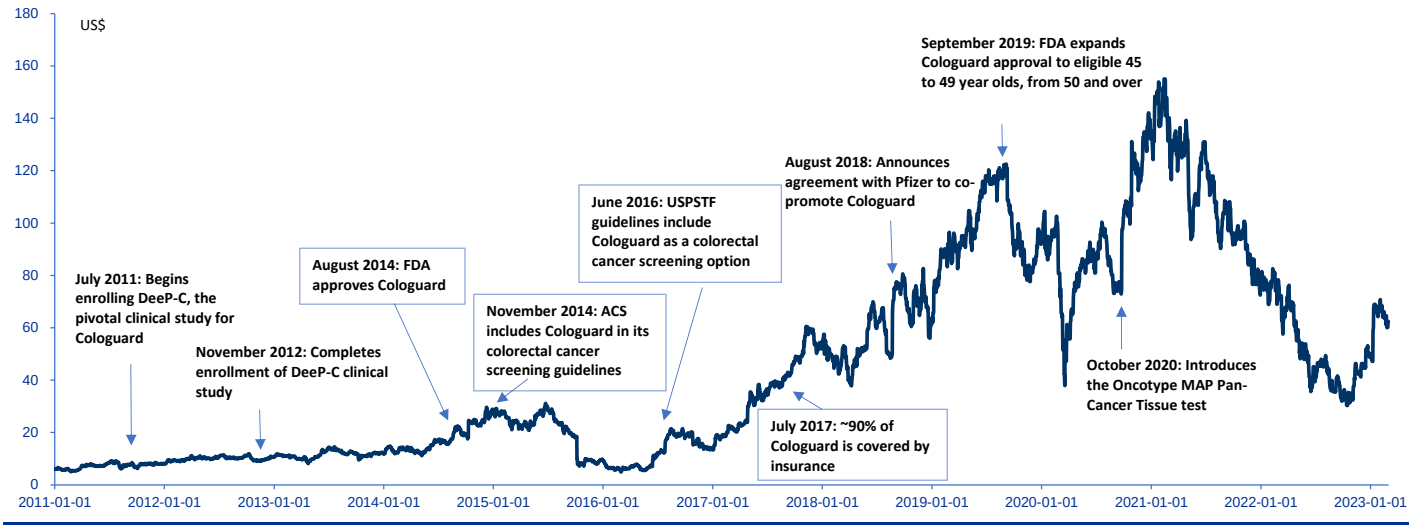
Figure 69: Summary of approved colorectal cancer screening products

Company	Product	Indication	Time of FDA approval	Time of NMPA approval	Technology	Sample type	Markers	Sensitivity	Specificity	PPV	NPV	Price
Exact Sciences	Cologuard	Colorectal cancer	Aug-14	-	FIT-DNA	Stool	DNA methylation, DNA mutation, Hb	Advanced adenoma: 42% Colorectal cancer: 92%	87%	24%	Advanced adenoma: 96% Colorectal cancer: ~100%	US$599
Epigenomics AG	Epi proColon	Colorectal cancer	Apr-16	-	Liquid biopsy	Blood	DNA methylation	81%	-	12-29%	~100%	-
NH Health	ColoClear	Colorectal cancer	-	Nov-20	FIT-DNA	Stool	DNA methylation, DNA mutation, Hb	Advanced adenoma: 64% Colorectal cancer: 95.5%	87%	46%	Advanced adenoma: 96% Colorectal cancer: ~100%	Rmb1,996
	Pupu Tube	Colorectal cancer	-	Mar-18	FIT	Stool	Hb	-	-	-	-	Rmb99

Source: Prospectus, NH's presentation (2023/02), DXY, FDA, SWS Research

Since Cologuard received the FDA's approval in August 2014, Exact Sciences' share price has increased rapidly with Cologuard added into the colorectal cancer screening guideline recommendations and insurance coverage. In November 2014 and June 2016, Cologuard was included into the colorectal cancer screening guidelines from the American Cancer Society (ACS) and the United States Preventive Services Task Force (USPSTF), respectively. In July 2017, around 90% of Cologuard users could use Medicare for payment.

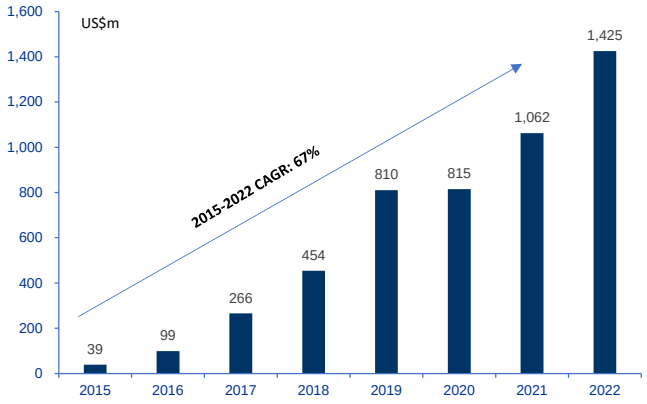
Figure 70: Review of Exact Sciences' share price performance since 2011



Source: Wind, Exact Sciences' official website, SWS Research

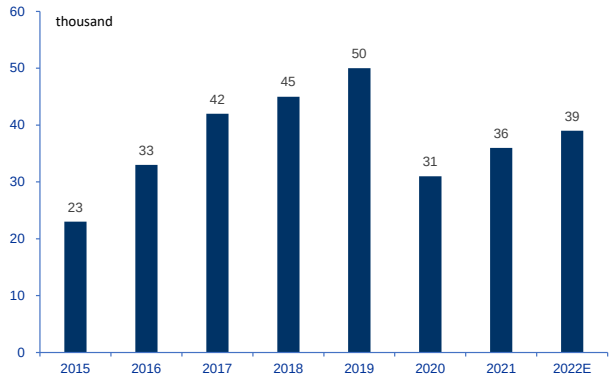
With the increasing product affordability, Cologuard's sales increased rapidly from US$39m in 2015 to US$1.42bn in 2022, with a Cagr of 67% from 2015 to 2022. In 2022, approximately 10m people used Cologuard for colorectal cancer screening. Besides, except for the impact of Covid-19 in 2020, the number of Cologuard's new providers has risen steadily, which is expected to increase by 39,000 new providers in 2022.

Figure 71: Cologuard's sales (2015-2022)



Source: Exact Sciences' annual reports, Exact Sciences' presentations, SWS Research

Figure 72: Number of Cologuard's new providers (2015-2022E)



Source: Exact Sciences' presentations, SWS Research

Both ColoClear and Cologuard use FIT-DNA technology to evaluate risk by targeting KRAS gene mutations, BMP3 and NDRG4 gene methylation and hemoglobin. Sensitivity and specificity are normally used as clinical indicators. Sensitivity, also known as "true positive rate", is the probability patients tested positive for cancer. The higher the sensitivity, the higher the "true positive rate" and the lower "error rate". In terms of the results for advanced adenoma and CRC of stage 1, ColoClear's sensitivities are 64% and 97%, respectively, significantly better than Cologuard's 42% and 90%, helping to detect the colorectal cancer earlier for early treatment.

Besides, high specificity can reduce the occurrence of false positives. Both the specificities of two products are c.87%. In addition, specificity, also known as "true negative rate", refers to the probability of not getting cancer in the patients with the negative results, so as to reduce the unnecessary follow-up examination of the healthy people with the positive results. The specificity of both those products is c.87%.

Figure 73: Comparison of clinical trial between ColoClear and Cologuard

			ColoClear	Cologuard
Samples			5,881	~10,000
Markers			KRAS gene mutations BMP3 and NDRG4 gene methylation Hb	KRAS gene mutations BMP3 and NDRG4 gene methylation Hb
Sensitivity	Advanced adenoma		64%	42%
	CRC	Stage 1	97%	90%
		Stage 2	98%	100%
		Stage 3	96%	90%
		Stage 4	96%	75%
		Unknown	86%	-
Specificity			87%	87%
NPV	Advanced adenoma		96%	96%
	CRC		100%	100%
PPV			46%	24%
Age group			40-75	45-75

Source: NH's 1H20 presentation, Cologuard's summary of safety and effectiveness, SWS Research

Currently, except for the ColoClear, the approved colorectal cancer testing products in China are all used for auxiliary diagnosis, which are used for patients who are recommended for colonoscopy, but cannot be used as proof for early tumor diagnosis or confirmation. These auxiliary diagnosis products only target single

or double gene methylation, while ColoClear combines KRAS gene mutations, BMP3 and NDRG4 gene methylation, as well as hemoglobin, with higher sensitivity and specificity than other products.

Figure 74: Summary of colorectal cancer auxiliary diagnosis products launched in China

Company	Product	Time of NMPA approval	Technology	Target(s)	Sample type	Price (Rmb)
Realbio	ColoWell	May-22	FIT-DNA	SFRP2 and SDC2 gene methylation	Stool	1,680
Ammunition	Icolocomf	Mar-22	FIT-DNA	SDC2 and TFPI2 gene methylation	Stool	1,200
AmoyDx	Changqinsong	Jan-21	FIT-DNA	SDC2 gene methylation	Stool	-
Creative Biosciences	Colosafe	Nov-18	FIT-DNA	SDC2 gene methylation	Stool	1,288

Source: Companies' official websites, NMPA, SWS Research

According to the data of Frost and Sullivan, and the National Bureau of Statistics, the population between 40 and 75 years old in China accounts for c.45% of the total population, among which approximately 20% are at high risk of colorectal cancer. Based on the rising penetration rate of early screening products among high-risk groups of colorectal cancer, the following table shows the sales forecast for ColoClear from 2023E to 2032E.

Figure 75: Sales forecast of ColoClear

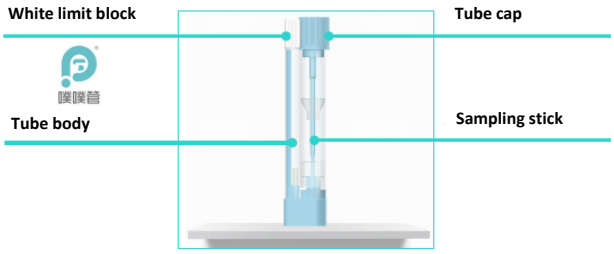
	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Population of China (million)	**1,418**	**1,421**	**1,424**	**1,425**	**1,427**	**1,428**	**1,430**	**1,431**	**1,432**	**1,434**
YoY %	*0.20%*	*0.20%*	*0.20%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*
The proportion of people aged 40-75 in China	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%
Population aged 40-75 in China (million)	638	639	641	641	642	643	643	644	645	645
% of high-risk population	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%	20.00%
High risk population aged 40-74 in China (million)	128	128	128	128	128	129	129	129	129	129
Penetration rate of ColoClear	0.33%	0.58%	1.13%	1.63%	2.13%	2.63%	3.13%	3.63%	4.13%	4.63%
Test once a year	1	1	1	1	1	1	1	1	1	1
Annual sales volume of ColoClear (million)	0.42	0.74	1.44	2.09	2.73	3.38	4.02	4.67	5.32	5.97
Annual treatment cost (Rmb)	1,796	1,617	1,455	1,310	1,179	1,061	933	821	723	636
Total (Rmbm)	**750**	**1,193**	**2,102**	**2,733**	**3,219**	**3,582**	**3,756**	**3,837**	**3,846**	**3,799**

Source: Frost and Sullivan, National Bureau of Statistics, SWS Research

3.2.2 Pupu Tube – Self-conducted screening product targeting at the average-risk colorectal cancer population

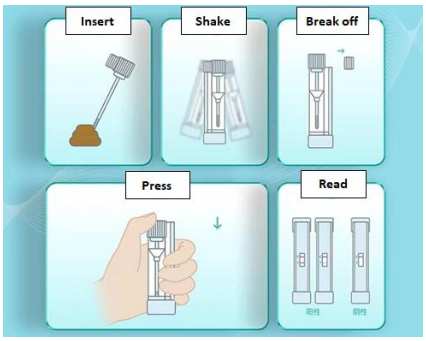
Pupu Tube is the company's self-developed non-invasive stool-based screening product using FIT technology, which can be tested at home. It can detect hemoglobin biomarkers related to the colorectal cancer. Pupu Tube is the first and only self-conducted FIT screening product approved by the NMPA in China. Pupu Tube consists of a sampling rod, a solution chamber and a test strip, allowing users to complete the test at home and to get the result after five minutes.

Figure 76: Product design of Pupu Tube



Source: NH's 1H22 presentation, SWS Research

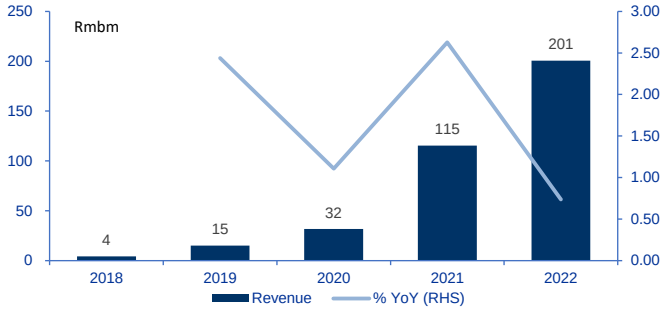
Figure 77: Pupu tube's testing methods



Source: NH's JD self-operated flagship store, SWS Research

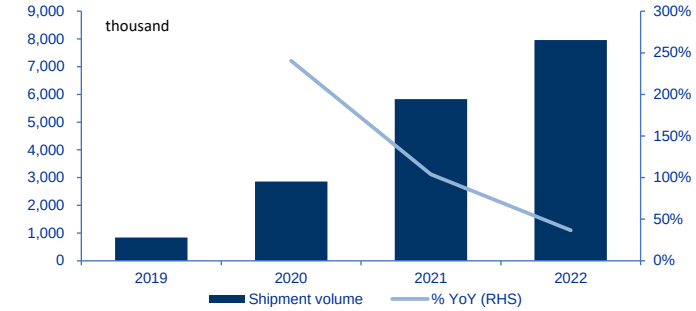
Pupu Tube targets at the average-risk populations who are recommended for the regular colorectal cancer screening. With the expanding penetration rate of DTC channel, we expect Pupu Tube to realize sales surge. In 2022, Pupu Tube's revenue and shipment volume reached Rmb69m (+74% YoY) and 7.96m units (+54% YoY).

Figure 78: Sales of Pupu Tube (2019-2022)



Source: Prospectus, NH's announcement of 2022 results, SWS Research

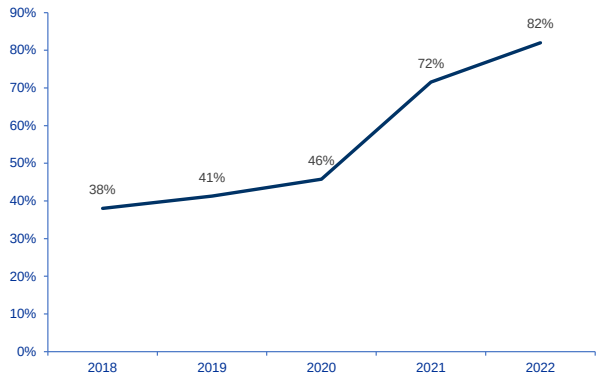
Figure 79: Shipment volume of Pupu Tube (2019-2022)



Source: Prospectus, NH's announcement of 2022 results, SWS Research

In addition, due to the rising income per test and decreasing production cost per unit, Pupu Tube's gross margin further climbed up from 72% in 2021 to 82% in 2022. We expect Pupu Tube's gross margin to stabilise at the current level.

Figure 80: Pupu Tube's gross profit (2018-2022)



Source: Prospectus, NH's announcement of 2022 results, SWS Research

According to the data of Frost and Sullivan and the National Bureau of Statistics, the population between 40 and 75 years old in China accounts for about 45% of the total population. Given the sales volume growth

from DTC channel with the increasing of public awareness of early screening, the following table shows the sales forecast for Pupu Tube from 2023E to 2032E.

Figure 81: Sales forecast of Pupu Tube

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Population of China (million)	**1,418**	**1,421**	**1,424**	**1,425**	**1,427**	**1,428**	**1,430**	**1,431**	**1,432**	**1,434**
YoY %	*0.20%*	*0.20%*	*0.20%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*
The proportion of people aged 40-75 in China	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%	45.00%
Population aged 40-75 in China (million)	638	639	641	641	642	643	643	644	645	645
Penetration rate of Pupu Tube	0.50%	0.70%	0.95%	1.45%	1.95%	2.45%	2.95%	3.45%	3.95%	4.45%
Test once a year	1	1	1	1	1	1	1	1	1	1
Annual sales volume of Pupu Tube (million)	3.16	4.44	6.06	9.27	12.49	15.71	18.95	22.19	25.43	28.68
Annual treatment cost (Rmb)	91	84	77	71	65	60	55	51	47	43
Total (Rmbm)	**288**	**372**	**467**	**657**	**815**	**943**	**1,046**	**1,127**	**1,189**	**1,233**

Source: Frost and Sullivan, National Bureau of Statistics, SWS Research

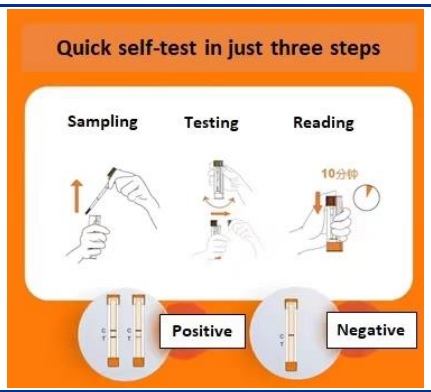
3.2.3 UU Tube – First self-conducted product for Helicobacter pylori screening

In January 2022, UU Tube was approved by NMPA as the first self-tested product for Helicobacter pylori (Hp) screening. The traditional stool antigen test (SAT) requires trained professionals to perform the test, while as an innovative self-conducted screening product, UU Tube can be used at home, with no limosis requirement. And the result can be read out within ten minutes, proving convenient.

Figure 82: Product design for UU Tube

Source: NH's 1H22 presentation, SWS Research

Figure 83: UU tube's testing methods



Source: NH's JD self-operated flagship store, SWS Research

Besides, the company focuses on the layout of online e-commerce platforms. Since the first launch of UU Tube on Alibaba Health, TMall Health, JD Health and Meituan-Medicine etc. on 18 January 2022, UU Tube's sales topped Rmb5.2m within 72 hours of launch on those online platforms. Thanks to the convenience and promotion on the e-commerce platforms, UU Tube's revenue and shipment volume reached Rmb210m and 3.35m units in 2022, respectively, with gross margin of 91%. In January 2023, the company entered a strategic partnership with Phase Scientific to jointly promote UU Tube in Hong Kong, at a price of HK$248.

Urea breath test (UBT) is the golden standard for Hp screening, and now the China market is short of effective stool antigen test (SAT). However, UBTs of C13 and C14 have some limitations prior to the testing, like the requirement of professional testing equipment, which takes a long time for the result. In comparison, UU Tube does not need any preparations before testing, and uses double antibody dissection technology to

test Hp in stool directly, enabling a wider range of application scenarios. In terms of pricing, the price for UU Tube is Rmb149 in the domestic market.

Figure 84: Comparison of UBT and SAT

	Preparation	Test method	Result time	Application scenario(s)	Price (Rmb)
Urea breath test (UBT)	1. Stop taking antibiotics, bismuth and acid-suppressing drugs 4 weeks prior to the test 2. Take urea capsules with isotopically labelled carbon atoms (C13 or C14) without eating or 2 hours after a meal	Indirect test: test isotopically labelled CO2 in the gas being collected	next day	Hospital	~200
Stool antigen test (SAT)	-	Direct test: Hp	5-10mins	Hospital, clinic, at-home	UU Tube: 149 (mainland China)

Source: Public information, DXY, SWS Research

At present, NH's UU Tube is mainly used to detect Helicobacter pylori antigen in stool samples, while CoWin Biosciences' Kangjianyou is based on the stool nucleic acids test. In addition, Kangjianyou is a non-home self-conducted product, which needs to send back samples to the laboratory for testing. UU Tube has the advantages of being first-mover and self-conducted at home compared with Kangjianyou.

Figure 85: Summary of part of Hp screening products

Company	Brand name	Product name	Type of NMPA approval	Indication	Time of NMPA approval	Target	Price (Rmb)
NH Health	UU Tube	Helicobacter pylori antigen detection reagent (emulsion process)	Class III medical device	GC	Jan-22	antigen	149
CoWin Biosciences	Kangjianyou	Helicobacter pylori nucleic acid Test Kit (PCR)	Class III medical device	GC	Dec-22	nucleic acids	298

Source: NH's announcements, VBDATA.CN, JD, NMPA, SWS Research

The *Guidelines for Screening and Early Diagnosis and Treatment of Gastric Cancer in China (2022, Beijing)* suggests that people aged 45-75 should be the target population for gastric cancer screening, which accounts for c.40% of the total population. Considering the sales volume growth from DTC channel with growing public awareness of Helicobacter pylori, the following table shows the sales forecast for UU Tube from 2023E to 2032E.

Figure 86: Sales forecast of UU Tube

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Population of China (million)	**1,418**	**1,421**	**1,424**	**1,425**	**1,427**	**1,428**	**1,430**	**1,431**	**1,432**	**1,434**
YoY %	*0.20%*	*0.20%*	*0.20%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*	*0.10%*
Proportion of population aged 45-75 in China	40.10%	40.20%	40.30%	40.40%	40.50%	40.60%	40.70%	40.80%	40.90%	41.00%
Population aged 45-75 in China (million)	569	571	574	576	578	580	582	584	586	588
Penetration rate of UU Tube	0.51%	0.71%	0.95%	1.45%	1.95%	2.45%	2.95%	3.45%	3.95%	4.45%
Test once a year	1	1	1	1	1	1	1	1	1	1
Annual sales volume of UU Tube (million)	2.92	4.08	5.47	8.37	11.29	14.23	17.19	20.17	23.17	26.19
Annual treatment cost (Rmb)	134	121	109	98	88	79	71	64	58	52
Total (Rmbm)	**392**	**492**	**595**	**819**	**993**	**1,127**	**1,225**	**1,294**	**1,337**	**1,360**

Source: Guidelines for Screening and Early Diagnosis and Treatment of Gastric Cancer in China (2022, Beijing), SWS Research

3.3 Strong pipeline

3.2.1 CerviClear – Self-conducted cervical cancer screening product

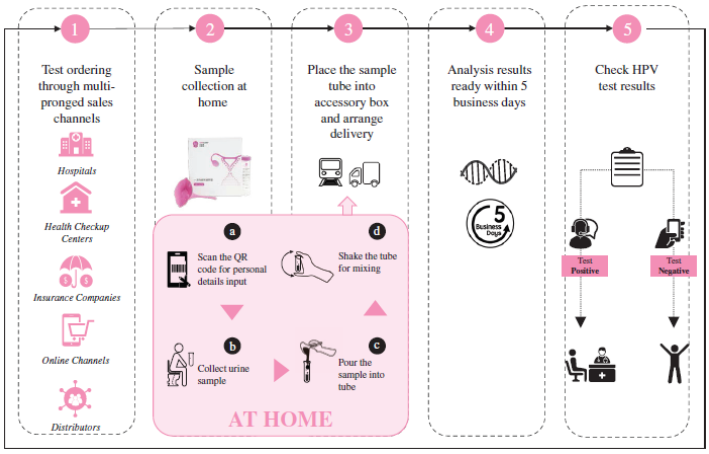
CerviClear is the company's self-developed home-use cervical cancer screening product based on urine samples. It can test for 14 high-risk HPV gene fragments simultaneously, including HPV 16 and HPV 18. In November 2022, CerviClear completed the first-patient-in and entered the registrational clinical stage officially. The trial is a large-scale prospective multicenter registration trial lasting for 3 years, with an estimated total enrollment of nearly 20k people.

At present, there is no non-invasive HPV DNA screening test using urine sample approved in the global market. All the FDA-approved products, like Roche's Cobas HPV kit, use vaginal cervical cells as samples, which require sampling of cervical epithelial cells. These tests are invasive and need to be screened in the hospital, with low patient compliance.

Figure 87: Product design for CerviClear

Source: Prospectus, SWS Research

Figure 88: CerviClear's testing process



Source: Prospectus, SWS Research

3.2.2 LiverClear – Liver cancer screening product covering DNA, RNA and protein

LiverClear is the company's self-developed liver cancer screening product, with cfDNA and cfRNA extracted from blood samples. After high-throughput sequencing, combined with multiple protein detection, molar integral was obtained with a patented artificial intelligence algorithm, and came to the final negative or positive result.

In September 2021, the company released the pre-research data in the 2021 CSCO. The result showed that both LiverClear's sensitivity and specificity reached 97.9% among the 645 patients, including 264 patients with liver cancer. The company expects to initiate a prospective multi-center clinical trial of LiverClear in 1Q23E.

Figure 89: Product design for LiverClear

Source: NH's official website, SWS Research

4. Earnings forecast

Given New Horizon Health's leading position in China's cancer screening market, rising market penetration rate, and low supply or inconvenient use of gold standard of screening methods, such as colonoscopy procedures or urea breath tests, we expect fast sales ramp-up of launched products. We expect the company's revenue to reach Rmb1.43bn (+87% YoY) in 23E, Rmb2.06bn (+44% YoY) in 24E and Rmb3.16bn (+54% YoY) in 25E, growing at a Cagr of 61% in 2022-25E.

Breaking down by products, we expect revenue of ColoClear to reach Rmb750m in 23E, Rmb1.19bn in 24E and Rmb2.10bn in 25E, growing at a Cagr of 81% during 2022-25E, with the sales ramp-up in hospitals. In addition, with the growing awareness of early cancer screening and increasing sales in DTC channel, we expect the revenue of Pupu Tube to grow at a Cagr of 33% in 2022-2025E, reaching Rmb288m in 23E, Rmb372m in 24E and Rmb467m in 25E. Besides, we forecast sales of UU Tube to reach Rmb392m in 23E, Rmb492m in 24E and Rmb595m in 25E, growing at a Cagr of 42% in 2022-2025E. Given that the pipeline products and projects are in the early development stage, our earnings forecast of 2023-25E have not yet included the CerviClear (cervical cancer), LiverClear (liver cancer), NPClear (nasopharyngeal cancer), etc.

In addition, considering the economies of scale and channel mix changes, we expect the blended gross margin to reach 86.0% in 23E, 86.4% in 24E and 87.0% in 25E. Meanwhile, with the rising revenue contribution from hospitals, we expect the gross margin of ColoClear to reach 85.0% in 23E, 86.0% in 24E and 87.0% in 25E. As for the Pupu Tube and UU Tube, we expect the gross margin to stabilise at 82.1% and 90.7% in 2023-25E, with a relatively stable sales channel.

Figure 90: Key financial assumptions

Revenue by product	2019	2020	2021	2022	2023E	2024E	2025E
Revenue (Rmbm)							
ColoClear	39	38	97	356	750	1,193	2,102
Pupu Tube	15	32	115	201	288	372	467
UU Tube	-	-	-	208	392	492	595
Other	4	1	0	1	-	-	-
Total	**58**	**71**	**213**	**765**	**1,430**	**2,058**	**3,163**
Revenue YoY							

ColoClear	171.2%	-3.9%	158.8%	266.2%	110.6%	59.1%	76.1%
Pupu Tube	243.8%	110.8%	262.7%	73.7%	43.4%	29.4%	25.3%
UU Tube	-	-	-	-	88.7%	25.6%	20.8%
Other	81420.0%	-71.5%	-93.2%	632.9%	-	-	-
Total	**41.7%**	**21.1%**	**201.5%**	**259.5%**	**86.9%**	**43.9%**	**53.7%**
Revenue mix							
ColoClear	67.1%	53.2%	45.7%	46.5%	52.5%	58.0%	66.4%
Pupu Tube	25.9%	45.1%	54.3%	26.2%	20.1%	18.1%	14.8%
UU Tube	-	-	-	27.2%	27.4%	23.9%	18.8%
Other	7.0%	1.6%	0.0%	0.1%	-	-	-
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Gross profit by product	2019	2020	2021	2022	2023E	2024E	2025E
Gross profit (Rmbm)							
ColoClear	27	25	74	297	637	1,026	1,828
Pupu Tube	6	15	83	165	236	306	383
UU Tube	-	-	-	188	355	446	539
Other	3	0	-0	-0	-	-	-
Total	**36**	**40**	**156**	**650**	**1,229**	**1,778**	**2,751**
Gross profit margin							
ColoClear	69.3%	66.9%	76.0%	83.4%	85.0%	86.0%	87.0%
Pupu Tube	41.3%	45.8%	71.5%	82.1%	82.1%	82.1%	82.1%
UU Tube	-	-	-	90.7%	90.7%	90.7%	90.7%
Other	63.7%	35.9%	-	-	-	-	-
Total	**61.6%**	**56.8%**	**73.4%**	**85.0%**	**86.0%**	**86.4%**	**87.0%**
Gross profit YoY							
ColoClear		-7.3%	194.2%	301.8%	114.6%	61.0%	78.2%
Pupu Tube		133.6%	466.8%	99.3%	43.4%	29.4%	25.3%
UU Tube		-	-	-	88.7%	25.6%	20.8%
Other		-83.9%	-	-	-	-	-
Total		**11.7%**	**289.2%**	**316.3%**	**89.1%**	**44.7%**	**54.7%**

Source: Prospectus, NH's announcement, SWS Research

5. Valuation

New Horizon Health is trading at 9x 23E PS and 6x 24E PS, vs 4x 23E PS and 4x 24E PS of its Hong overseas peers, and 7x 23E PS and 6x 24E PS of A-share peers on average. We believe the company deserves a valuation premium to its Hong Kong-listed peers thanks to the scarcity of its business and its promising growth outlook.

Based on a discounted cash flow (DCF) model, we arrive at a target price of HK$55.1. With 75% upside, we initiate coverage with a BUY recommendation. Our assumptions include a weighted average cost of capital (WACC) of 9.82% and a terminal growth rate of 3.50%.

Figure 91: Comparable peers of New Horizon Health

Company name in English	Company name in Chinese	Ticker	Rating	Market cap (Rmbm)	PE			PS		
					23E	24E	25E	23E	24E	25E
New Horizon Health	**诺辉健康**	**06606.HK**	**BUY**	**1,941**	**-**	**54**	**23**	**9**	**6**	**4**
Overseas peers										
EXACT SCIENCES CORP	精密科学	EXAS.O	N/R	12,031	-	-	-	5	5	4
GUARDANT HEALTH INC	-	GH.O	N/R	3,293	-	-	-	6	5	4

BURNING ROCK BIOTECH LTD-ADR	燃石医学	BNR.O	N/R	352	-	-	-	3	3	2
GENETRON HOLDINGS LTD-ADR	泛生子	GTH.O	N/R	90	-	-	-	1	1	1
EPIGENOMICS AG	-	ECX.DF	N/R	3	-	-	-	4	4	3
Overseas peers average					**-**	**-**	**-**	**4**	**4**	**3**
A-share listed peers										
BGI GENOMICS CO LTD-A	华大基因	300676.SZ	N/R	3,494	13	-	-	-	-	-
AMOY DIAGNOSTICS CO LTD-A	艾德生物	300685.SZ	N/R	1,728	40	31	-	11	9	-
TELLGEN CORP-A	透景生命	300642.SZ	N/R	546	18	14	-	4	3	-
A-share peers average					**18**	**23**	**-**	**7**	**6**	**-**

Source: Bloomberg, SWS Research. Note: We use Bloomberg consensus for non-rated stocks, market data (as of 2023/3/20).

Figure 92: DCF valuation

(Rmbm)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	Terminal value
Ebit	-14.527	316.089	670	1,046	1,403	1,748	2,045	2,310	2,479	2,614	
Tax rate	-	15.00%	15.00%	15.00%	15.00%	15.00%	15.00%	15.00%	15.00%	15.00%	
EBIT*(1-tax rate)	-	268.676	569.571	889	1,192	1,486	1,738	1,964	2,107	2,222	
+ D&A	18	18	12	12	12	12	12	12	12	12	
- Change in working capital	36.1663	-225.81	4.65765	-162.25	-76.824	-10.114	54.3634	90.2509	114.579	133.279	
- Capx	-35	-35	-32	-32	-32	-32	-32	-32	-32	-32	
Free cash flow (FCF)	19.1663	25.8619	554.229	707	1,095	1,455	1,772	2,034	2,202	2,335	36,052
Terminal growth rate	3.50%										
WACC	9.82%										
Present value of FCF (Rmbm)	20,331										
Net debt (Rmbm)	-1838.4										
Equity value (Rmbm)	22,169										
Total shares outstanding (mn)	457.545										
Value per share (Rmb)	48.4528										
Value per share (HK$)	**55.06**										

Source: SWS Research

Figure 93: DCF sensitivity analysis of NH's share price (HK$)

		Terminal growth rate				
		3.00%	**3.50%**	**4.00%**	**4.50%**	**5.00%**
WACC	**8.50%**	66.63	71.40	77.23	84.52	93.89
	9.00%	60.45	64.27	68.85	74.44	81.43
	9.50%	55.25	58.35	62.01	66.40	71.77
	10.00%	50.81	53.36	56.34	59.85	64.07
	10.50%	46.99	49.11	51.55	54.41	57.78

Source: SWS Research

6. Catalysts

1) Business: Rising contribution from hospitals and DTC; higher-than-expected sales ramp-up.

2) Policy: CerviClear completed the patient enrollment in 23E; LiverClear to initiate the prospective clinical trials in 23E.

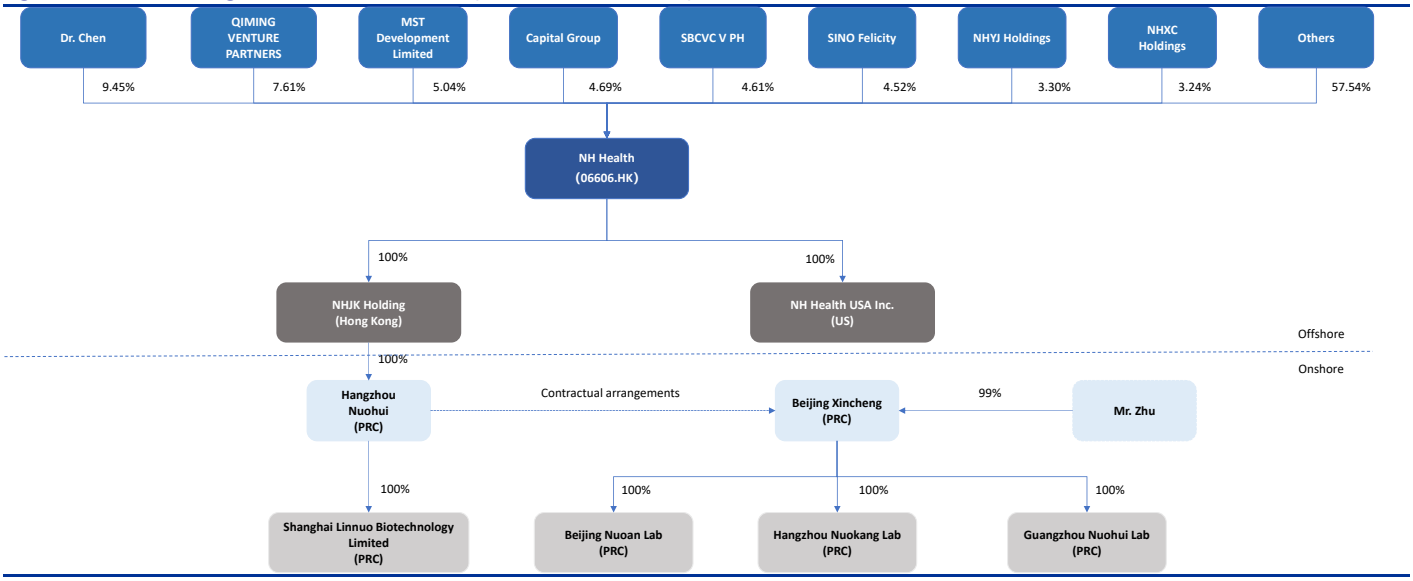
7. Risks

1) Business: Rising competition in the cancer screening market; lower-than-expected penetration rate.

2) Policy: Slower-than-expected pipeline progress.

Appendix

Figure 94: Shareholding structure of NH Health (as of March 20, 2023)



Source: Prospectus, Bloomberg, Wind, SWS Research

Company Financials

Consolidated Income Statement

Rmbm	2021	2022	2023E	2024E	2025E
Revenue	**213**	**765**	**1,430**	**2,058**	**3,163**
Cost of Sales	**(58)**	**(119)**	**(201)**	**(280)**	**(412)**
Gross Profit	**155**	**646**	**1,229**	**1,778**	**2,751**
Other Income	**23**	**16**	**16**	**16**	**16**
Selling/General/Admi. Expenses	(381)	(715)	(1,089)	(1,242)	(1,593)
Ebitda	(3,035)	(54)	3	334	682
Ebit	(3,078)	(72)	(15)	316	670
Finance Costs	(8)	(7)	(29)	(41)	(16)
Profit before tax	**(3,085)**	**(80)**	**(43)**	**275**	**654**
Income tax expense	0	(1)	0	(41)	(98)
Minority interests	0	0	0	0	0
Profit for the year	**(3,085)**	**(80)**	**(43)**	**234**	**556**

Source: SWS Research

Consolidated Cash Flow Statement

Rmbm	2021	2022	2023E	2024E	2025E
Profit before taxation	**(3,085)**	**(80)**	**(43)**	**275**	**654**
Plus： Depr. and amortisation	43	18	18	18	12
Finance cost	8	7	29	41	16
Losses from investments	43	0	0	0	0
Change in working capital	(137)	(361)	36	(226)	5
Others	2,774	(1)	0	(41)	(98)
CF from operating activities	**(355)**	**(416)**	**40**	**67**	**589**
Capex	(37)	(35)	(35)	(35)	(32)
Other CF from investing activities	(1,150)	0	0	0	0
CF from investing activities	**(1,187)**	**(35)**	**(35)**	**(35)**	**(32)**
Equity financing	1,956	0	702	0	0
Net change in liabilities	(37)	0	0	0	0
Dividend and interest paid	(8)	(7)	(29)	(41)	(16)
Other CF from financing activities	(127)	0	0	0	0
CF from financing activities	**1,784**	**(7)**	**673**	**(41)**	**(16)**
Net cash flow	**242**	**(458)**	**678**	**(9)**	**541**
FCFF	(3,209)	(451)	5	32	557
FCFE	(3,253)	(458)	(24)	(9)	541

Source: SWS Research

Consolidated Balance Sheet

Rmbm	2021	2022	2023E	2024E	2025E
Current Assets	2,059	2,001	2,671	2,942	3,592
Bank balances and cash	687	1,131	1,809	1,800	2,341
Trade and other receivables	134	584	548	789	867
Inventories	59	71	99	138	169
Other current assets	1,180	215	215	215	215
Long-term investment	9	10	10	10	10
PP&E	61	82	102	122	142
Intangible and other assets	224	482	479	476	476
Total Assets	**2,354**	**2,575**	**3,263**	**3,550**	**4,220**
Current Liabilities	193	227	256	310	424
Borrowings	79	0	0	0	0
Trade and other payables	39	109	137	192	305
Other current liabilities	75	119	119	119	119
Long-term liabilities	34	226	226	226	226
Total Liabilities	**227**	**453**	**482**	**536**	**650**
Minority Interests	0	0	0	0	0
Shareholder Equity	2,127	2,122	2,781	3,014	3,570
Share Capital	0	0	0	0	0
Reserves	(4,286)	(4,298)	(3,639)	(3,405)	(2,849)
Total Equity	2,127	2,122	2,781	3,014	3,570
Total Liabilities and equity	**2,354**	**2,575**	**3,263**	**3,550**	**4,220**

Source: SWS Research

Information Disclosure:

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