

# Genetron Holdings Limited

(Nasdaq: GTH)

## 1Q 2022 Financial Results

June 2022

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## TAM: Diagnosis & Monitoring

### LDT + IVD

**Diagnosis: \$6.7B<sup>1</sup>**  
**MRD: \$14B<sup>2</sup>**

LDT – Top player covering 500+ hospitals

IVD – 7 products approved;  
S5 + Lung 8 NGS solution

MRD partnerships in blood and solid tumors



**FOSUN PHARMA**  
复星医药

### Biopharma Services

**Biotech Industry: \$0.5B<sup>1</sup>**

High growth Chinese biotech industry

#1 Ranking: 64 total biopharma partners

CDx demand is growing as NMPA increases focus on genomic testing for innovative drugs



## TAM: Early Screening

**Liver cancer: \$7.2B<sup>1</sup>**  
**CRC cancer: \$23.0B<sup>1</sup>**  
**Lung cancer: \$5.8B<sup>1</sup>**

HCCscreen™ –

- FDA breakthrough device designation (NGS)
- Leading prospective data
- Commercialization roadmap

HCCscan™ –

- PCR-based assay expands market opportunity leveraging existing customer capabilities

Multi-cancer development with innovative technology in liquid biopsy

## Our Proprietary Technology: One-step Seq, Mutation Capsules

1. Frost & Sullivan, Market potential in China as of 2023
2. Euromonitor, Globalcan, Company internal estimates market potential

- Recent Events & Business Updates
- 1Q 2022 Financials
- Milestones and Growth Strategy
- Appendix



## Revenue growth with strong in-hospital sales momentum

- In 1Q2022, total revenue was RMB 110.3 million, representing 19.8% yoy growth
  - Revenue from LDT services increased by 13.5% yoy to RMB 81.5 million
  - Revenue from IVD products increased by 18.1% yoy to RMB 18.0 million. Ended 1Q with 33 IVD contracts
  - Revenue from development services increased by 117.2% yoy to RMB 10.8 million

## Early-screening business with first-mover advantage

- Successfully launched HCC early screening test in China, broadened registrational strategy –
  - HCCscan™ (PCR assay) – 5 clinical sites started patient enrollment
  - HCCscreen™ (NGS assay) – reported data from large-scale prospective study, registration trial enrollment to begin in 3Q2022

## Leading position in MRD, CDx and others

### MRD:

- Seq-MRD® detection kit for hematologic cancers has received CE Mark and started clinical launch
- Publication in *Clinical and Translational Medicine*, demonstrated Mutation Capsule™'s potential in MRD assay developments

### CDx:

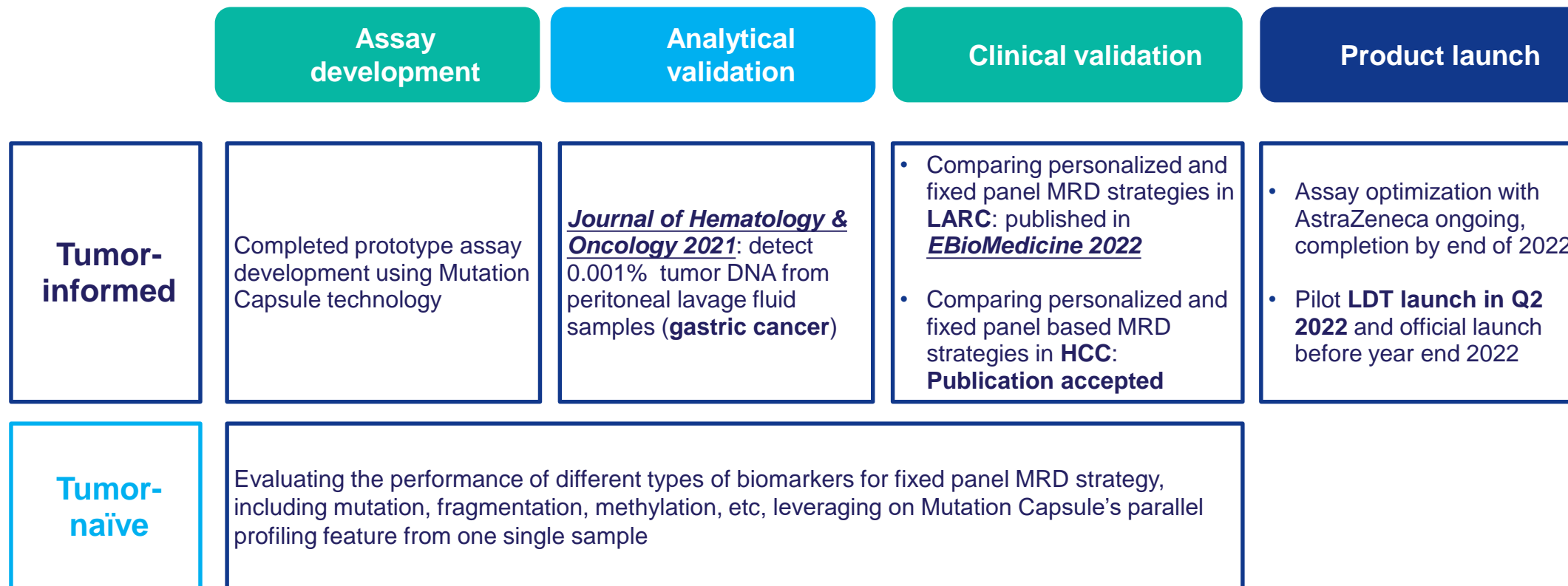
- HUTCHMED: ORPATHYS® for NSCLC in China, using 8-gene lung cancer assay
- Cstone: AYVAKIT® in China, which has entered the NMPA priority review process
- Received CE mark for FusionScan Plus, which uses integrated DNA and RNA as templates for genetic alteration detection

### Others:

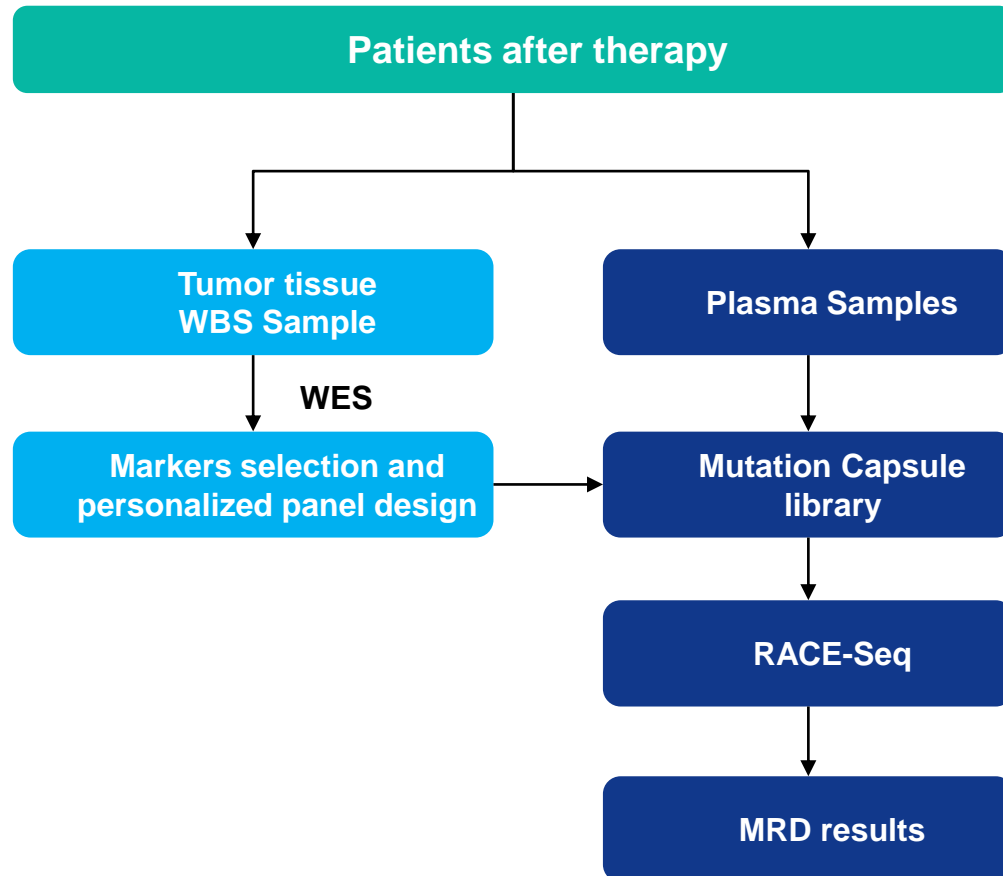
- AACR 2022: presented 17 new research results from joint studies with 20+ leading hospitals in China, including "One-step Seq" technology, core products such as Onco PanScan™ and Onco PanScan plus™

	Assay development	Clinical validation	Product launch
HCCscreen	<ul style="list-style-type: none"> <li>Multi-omics NGS assay powered by innovative and proprietary Mutation Capsule Technology</li> <li>U.S. FDA Breakthrough Device Designation</li> </ul>	<ul style="list-style-type: none"> <li>Mar 2019, China's first prospective (331 HBsAg+ patient cohort) and peer-reviewed study on HCC early screening <u>PNAS</u></li> <li>Mar 2021, investigational study (the "HIT" study) data readout: superior sensitivity and comparable specificity versus stand-of-care</li> </ul> <div> <ul style="list-style-type: none"> <li>Initiation of HCCscreen registrational trial in 2022</li> <li>Ongoing U.S confirmatory study</li> </ul> </div>	<ul style="list-style-type: none"> <li>LDT partnership with iKang Group to cover 100+ health check centers</li> <li>Collaboration with local government for public health initiatives (Wuxi and Dafang)</li> <li>Collaboration with digital health platforms and pharma partners</li> <li>Lab co-development within hospitals</li> </ul>
HCCscan	<ul style="list-style-type: none"> <li>PCR-based multi-methylation marker assay</li> </ul>	<ul style="list-style-type: none"> <li>HCCscan registrational trial initiated in 4Q21</li> <li>5 sites already started</li> </ul>	

# Solid-tumor MRD development plan



- Co-development for a personalized MRD assay for various solid tumor types in China
- This approach may help in the clinical management of patients far before metastatic lesions grow to significant size that detectable by conventional methods such as MRI and CT scanning
- AZ will incorporate the co-developed assay for China-specific studies.
- First step of a multi-year, exclusive LT partnership. Room to expand to IVD and commercialization



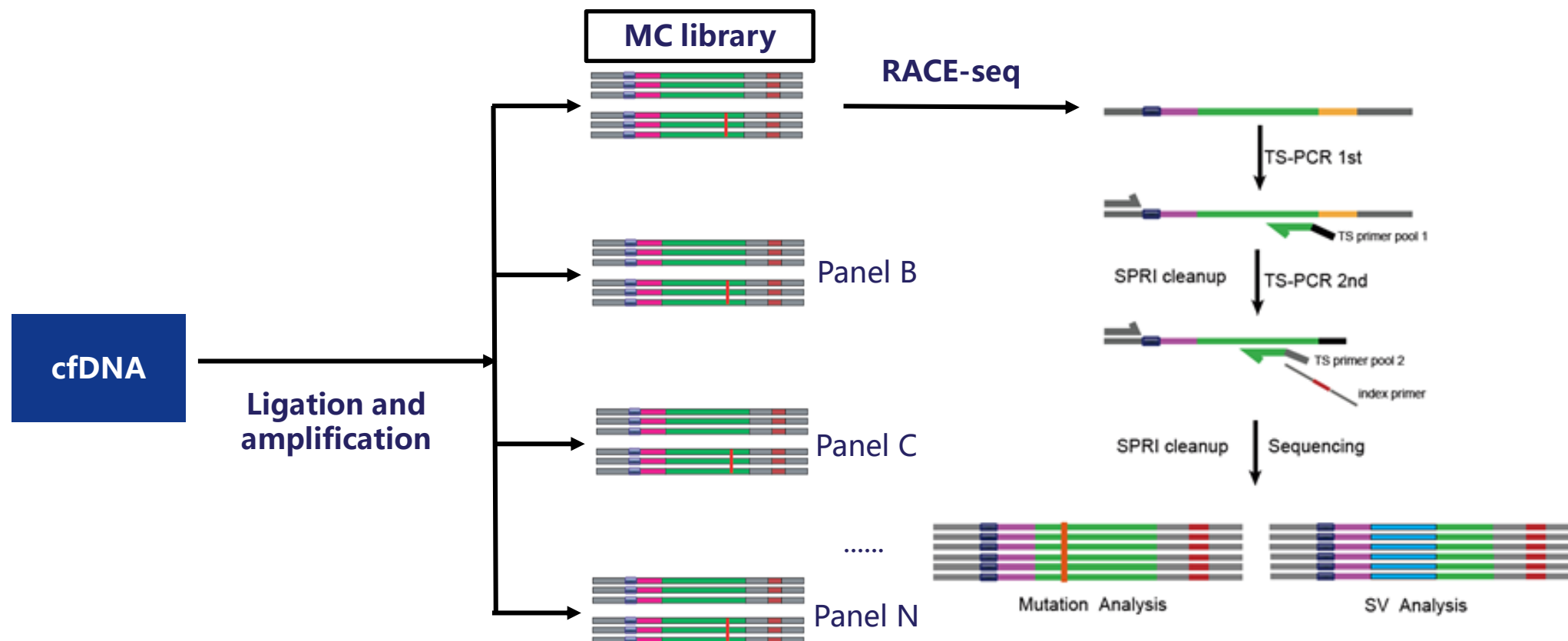
## Methodology

- Select mutation markers based on WES of tumor tissue, design personalized panel for subsequent blood-based ctDNA testing
- **Advantage:** maximize performance, avoid false positive and false negative as much as possible
- **Disadvantage:** high cost, long design process and require tumor tissue sample





# Advantage of Mutation Capsule in Solid-tumor MRD



## Tumor-informed MRD

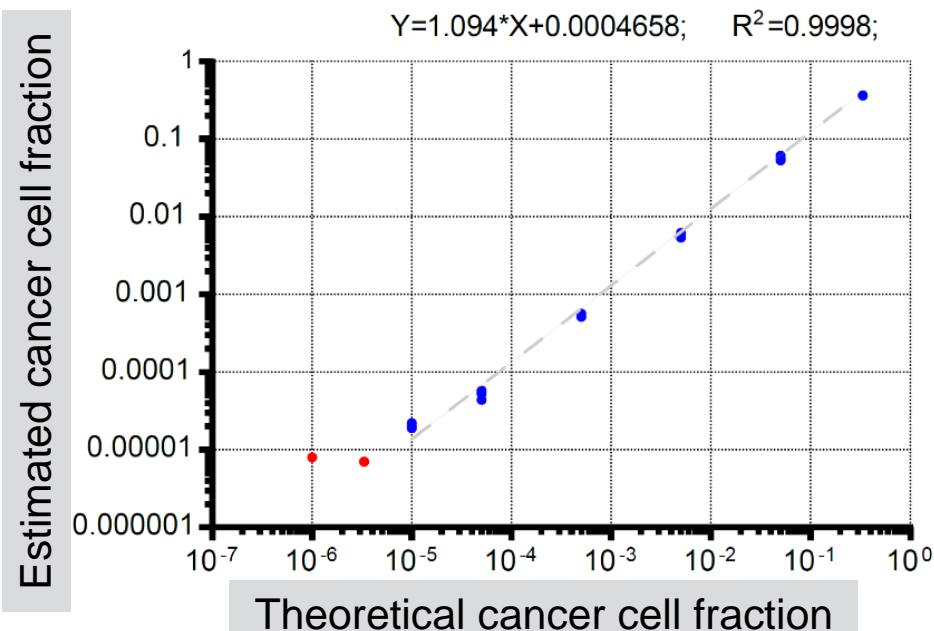
- Almost 100% success rate for personalized panel design from WES on the first try
- Support multiple tests from one single sample, therefore significantly reduces panel validation time

## Tumor-naïve MRD

- Support different types of biomarkers for tumor-naïve MRD panel design, including mutation, methylation, fragmentation etc.
- Support head-to-head comparison of tumor-naïve MRD panels with personalized MRD panel

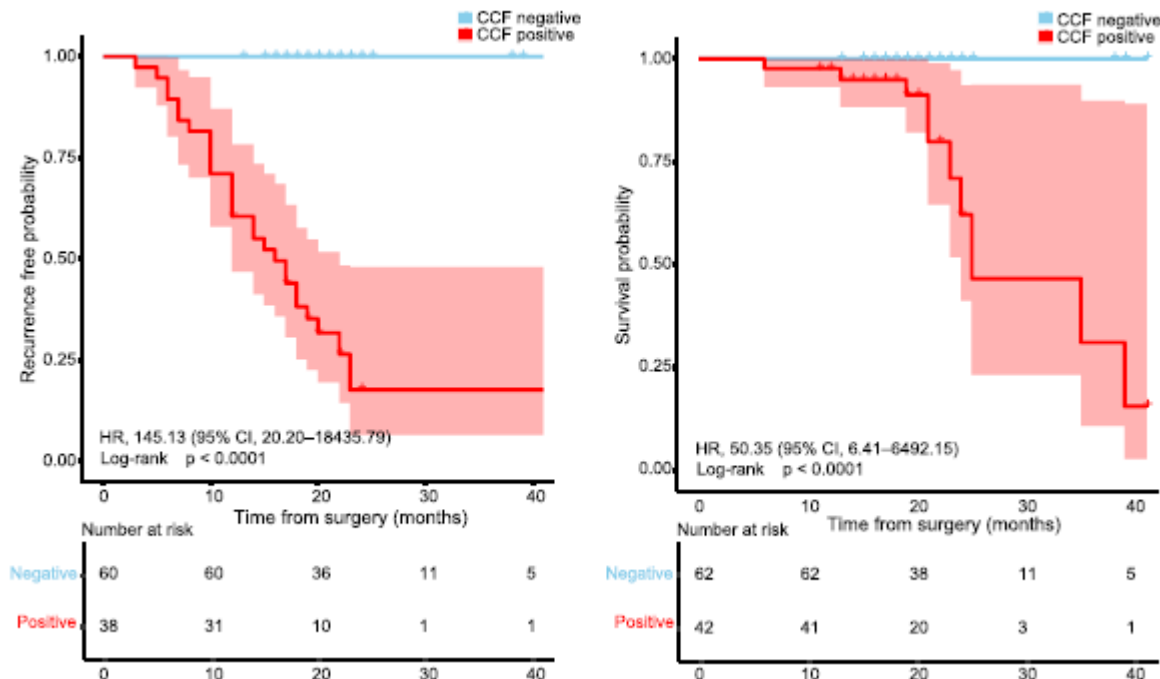
## Validated ctDNA fraction model

- A mutation-based personalized MRD assay was developed to detect residual cancer cells from peritoneal lavage fluid
- Exhibited high sensitivities with strong linear correlation between theoretical and estimated cancer cell dilution ratios up to 0.001%



## Analytical validation in gastric cancer

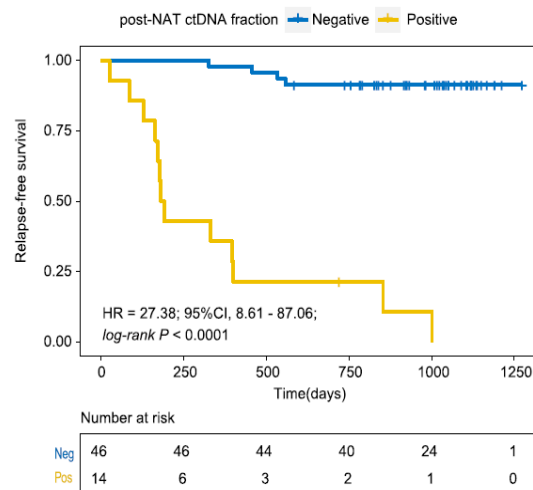
- In a prospective cohort of 104 Gastric cancer (GC) patients, the MRD assay detected all the cases that developed peritoneal dissemination (PD) with 100% sensitivity and 85% specificity
- MRD-positive patients were associated with decreased recurrence free survival (RFS) and overall survival



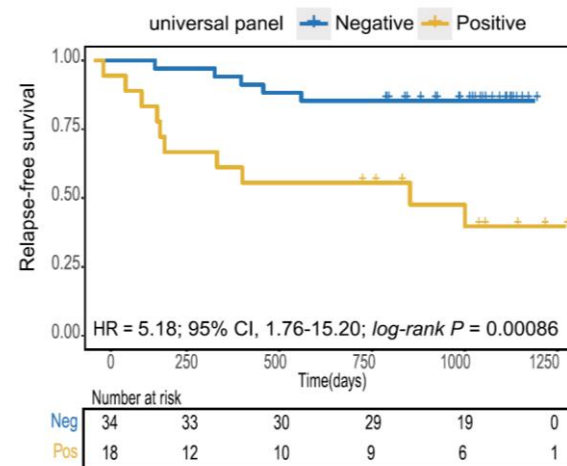
Zhao, D., Yue, P., Wang, T. et al. *J Hematol Oncol* 14, 164 (2021).

Head-to-head comparison between personalized and non-personalized assays in rectal cancer patients

Personalized panel



Fixed panel

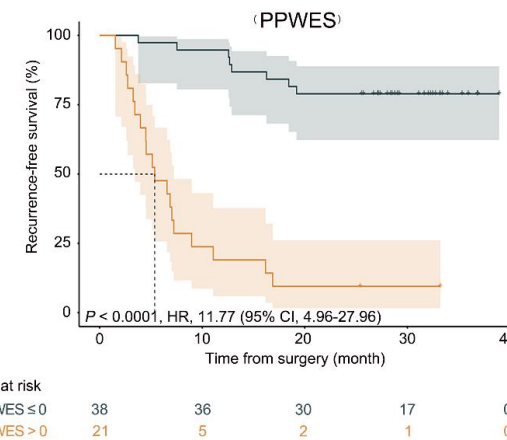


Published on EBioMedicine

Head-to-head comparison between personalized and non-personalized assays in HCC patients

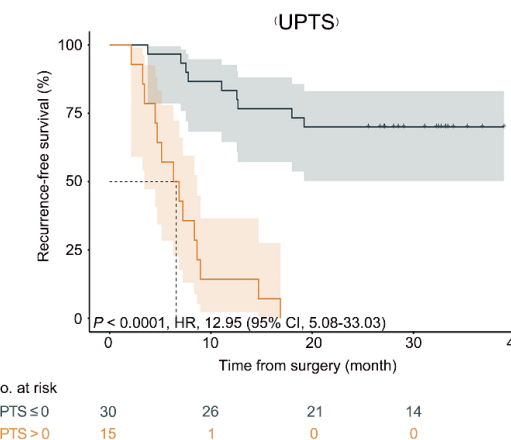
Personalized panel

HR=12; P<0.0001



Fixed panel

HR=13, P<0.0001

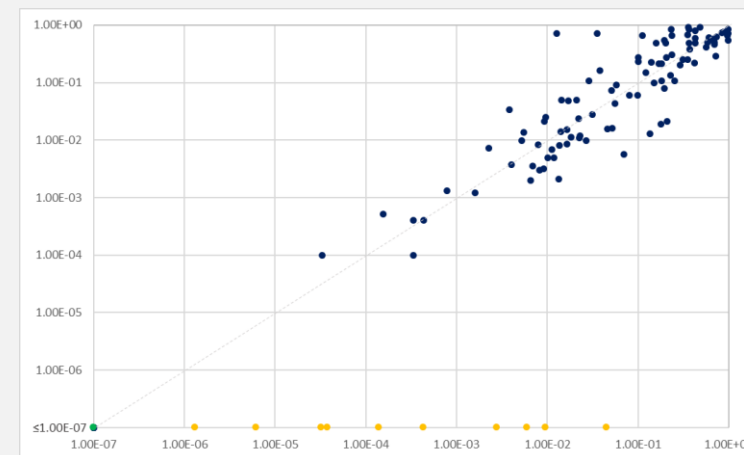


Published on Clinical and Translational Medicine

Enabled by One-step Seq + fully automated bioinformatics solutions

Higher sensitivity compared with FCM

- In the performance verification test for ALL, CLL and MM, when loading 20µg sample
  - For ALL and MM sample, the LOD (Limit of Detection) is  $6.5 \times 10^{-7}$
  - For CLL sample, the LOD (Limit of Detection) is  $9.75 \times 10^{-7}$
- Based on validation data from 128 clinically confirmed patients' samples (including 47 B-ALL, 39 CLL, and 42 MM). The positive detection results of traditional flow cytometry (FCM) and Seq-MRD were highly consistent
- Among them, 10 cases were detected MRD positive by Seq-MRD but negative by FCM, which reflected the **higher sensitivity** of Seq-MRD



	FCM MRD+	FCM MRD-	PPA (95%CI)	NPA 95%CI)
Seq-MRD+	98	10	100% (96.23%-100%)	66.67% (48.78%-80.77%)
Seq-MRD-	0	20		

Initiated commercialization in China

GENETRON 泛生子 X FOSUN PHARMA  
复星医药

- Exclusively collaborating with Fosun Pharma in hematologic-focused hospitals and clinics in China
- Fosun has 1,500 sales reps to sell innovative drugs that target hematologic and lymphoid malignancies, and solid tumors

ALL: acute lymphoblastic leukemia MM: multiple myeloma CLL: chronic lymphoid leukemia

# #1 in Drug Development Services for Biopharma



- Strategic partnerships with **64** leading global and Chinese biopharma companies
- Continue to see a strong pipeline as to form partnerships through our key products including **Seq-MRD**, **Onco Panscan**, **Fusion Scan**, etc.


## Global clinical drug trials and CDx development

- CLIA lab in Maryland, US - a solid platform to offer services for cross-border trials and CDx developments
- Strategic partnership with NeoGenomics 

CDx: Companion diagnostics


Note: Partner number as of March 31, 2022

# 8-Gene Kit + S5 Instrument - Efficient Solution for Hospitals



CE

**Lung Cancer 8-Gene Kit** + **Genetron S5**



**Accurate Testing** High sequencing consistency, repetition rate and accuracy

**Speedy Process** 2-day turn around time

**Small Sample Demand** As little as 20ng of sample DNA

## Comprehensive 8-gene coverage

Gene	Chinese population mutation rate <sup>1</sup>
EGFR	50.1%
KRAS	12.3%
BRAF	4.4%
PIK3CA	12%
HER2	6.3%
ALK	7.8%
ROS1	1.3%
MET	3.4%

1. Oncologist. 2019 Nov;24(11):e1070-e1081.

## Target at China hospital market

Teamed up with Siemens Healthineers to advance the use of Genetron S5 platform and lung cancer 8-gene IVD assay in hospitals market



## New commercialization opportunity

Received CE Mark for 8-gene Lung Cancer Assay, the second regulatory milestone for this assay

## CDx development collaboration

Partnered with HUTCHMED for Orpathys (savolitinib) in China





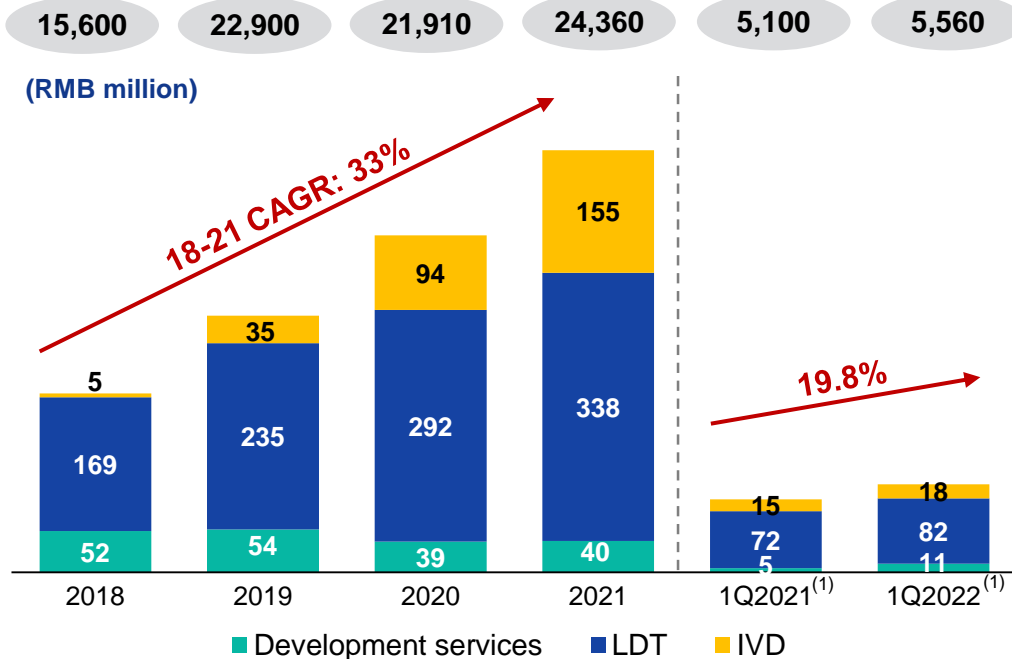
- Recent Events & Business Updates
- **1Q2022 Financials**
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# 1Q 2022 Revenue

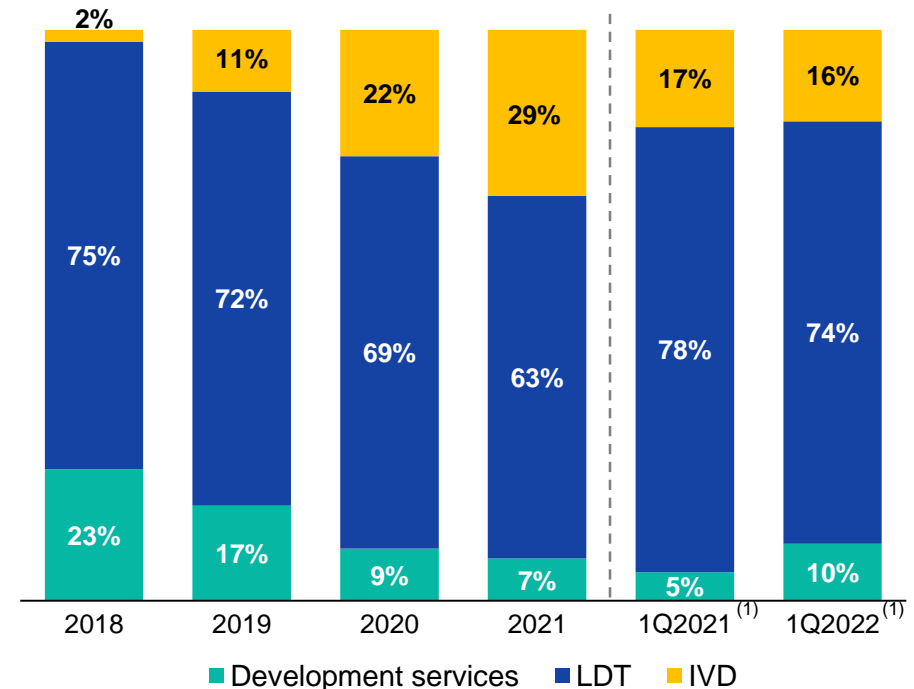
- LDT diagnostic test volume grew 9% YOY
- Increased IVD revenue was driven by Genetron S5 instrument and 8-gene Lung Cancer Assay
- Development services: driven by growth in sequencing and biopharma services revenues

## Revenue growth in 1Q2022

# of LDT diagnostic tests



## IVD revenue as a percentage of total revenue increased in 1Q2022



Note:  
(1) Unaudited financial numbers

## “LDT + IVD” Business Model

### Laboratory developed test (LDT)

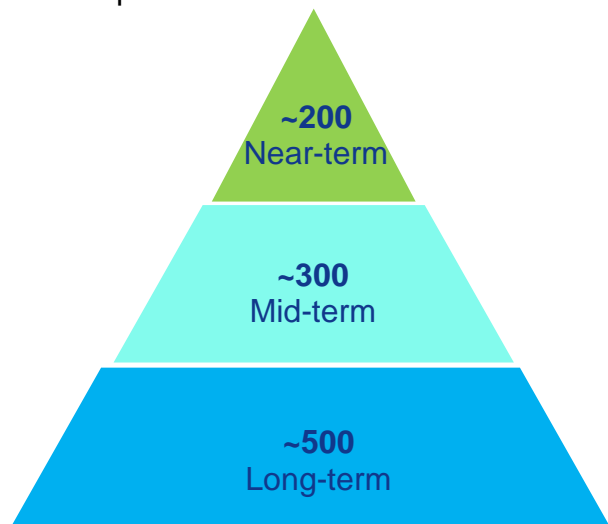
- Initially hospitals unable to run complex NGS testing in house
- Third party labs provide service to hospitals
- Fast adoption of latest technology



### In vitro diagnostics (IVD)

- Generate incremental revenue for hospitals
- Currently the only pathway to public medical insurance
- Lengthy large size clinical trials required by NMPA

Targeting ~1000 Class 3 Grade A hospitals for cancer treatment in China



**350+** internal direct sales and marketing rep

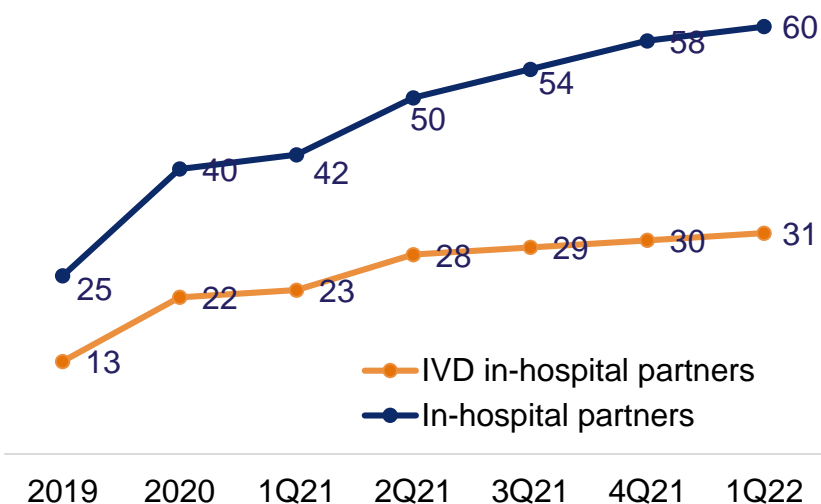
Teamed up with Siemens Healthineers to advance the use of Genetron S5 platform and lung cancer 8-gene IVD assay in hospitals

**500+** hospitals ordered tests from us

**60** in-hospital partners<sup>(1)</sup> including **31** IVD In-hospital partners<sup>(2)</sup>

(1) The number of total in-hospital partners include both sales of LDT services and IVD products.  
(2) By December 31, 2021

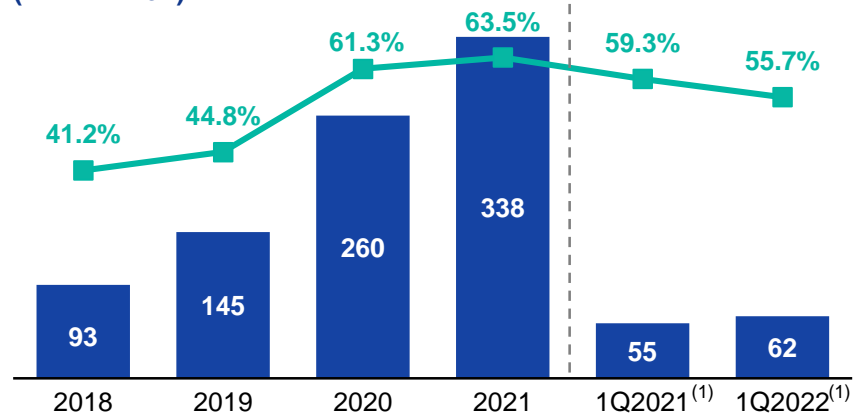
Number of In-hospital Partners



# 1Q 2022 Gross Margin

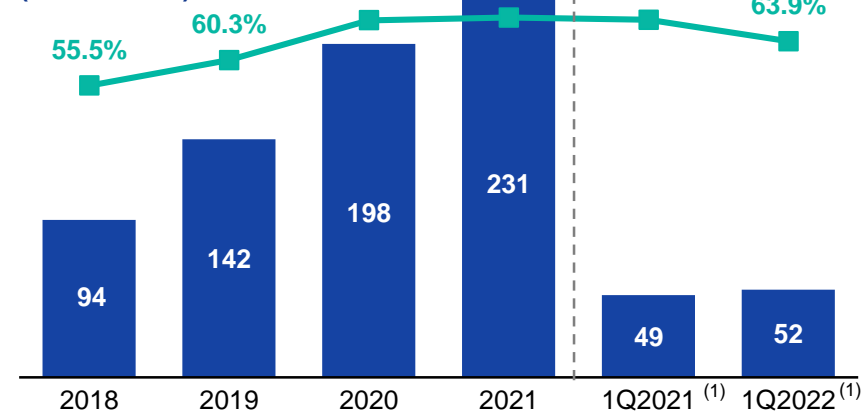
## Gross profit and margin

(RMB million)



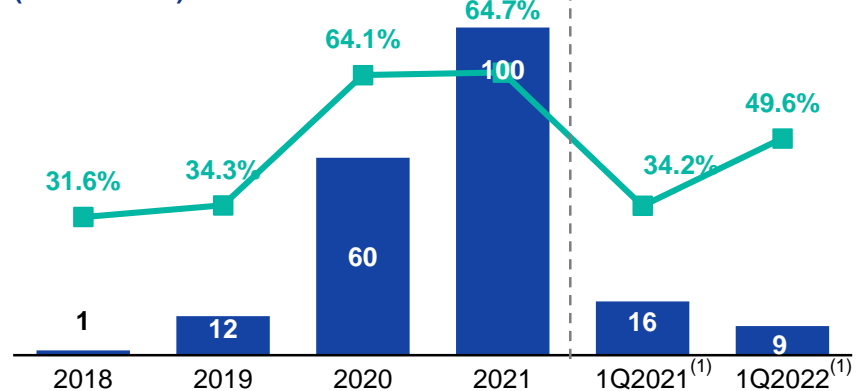
## Gross profit and margin (LDT)

(RMB million)



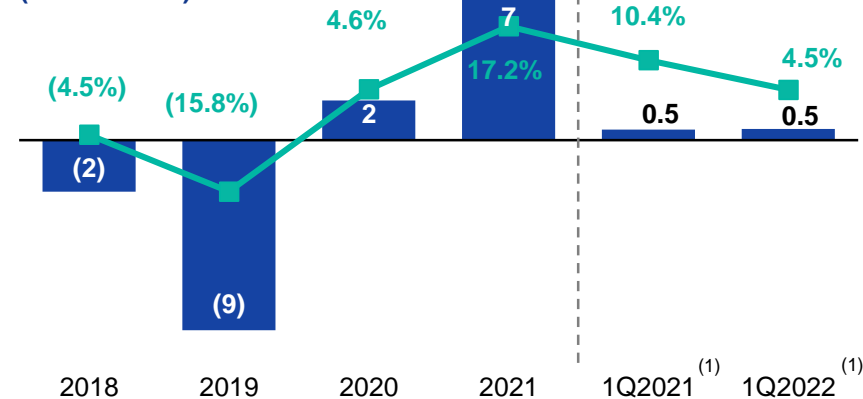
## Gross profit and margin (IVD)

(RMB million)



## Gross profit and margin (Development services)

(RMB million)

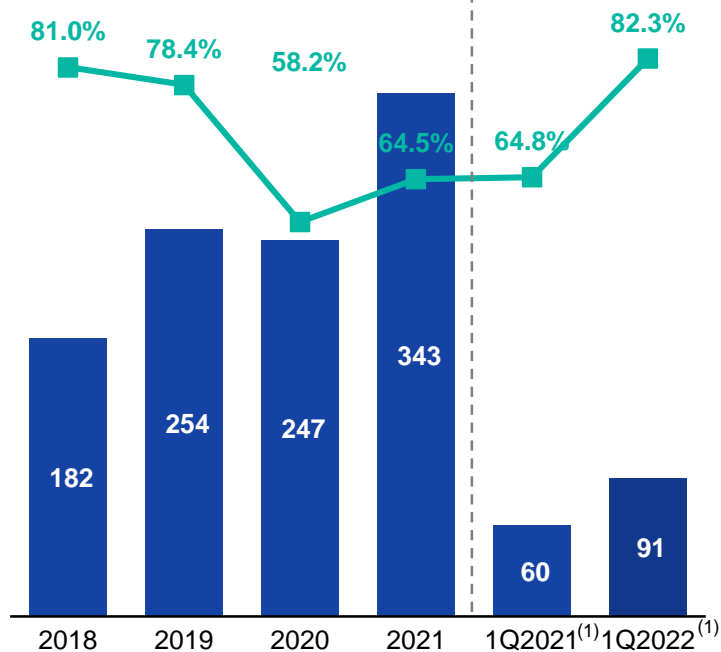


Note:  
(1) Unaudited financial numbers

# 1Q 2022 Operating expenses

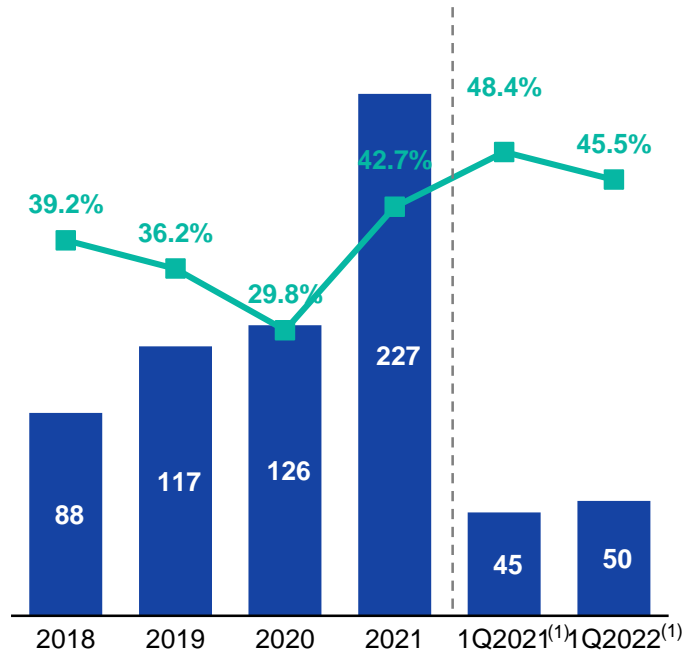
## Selling expenses

(RMB million)



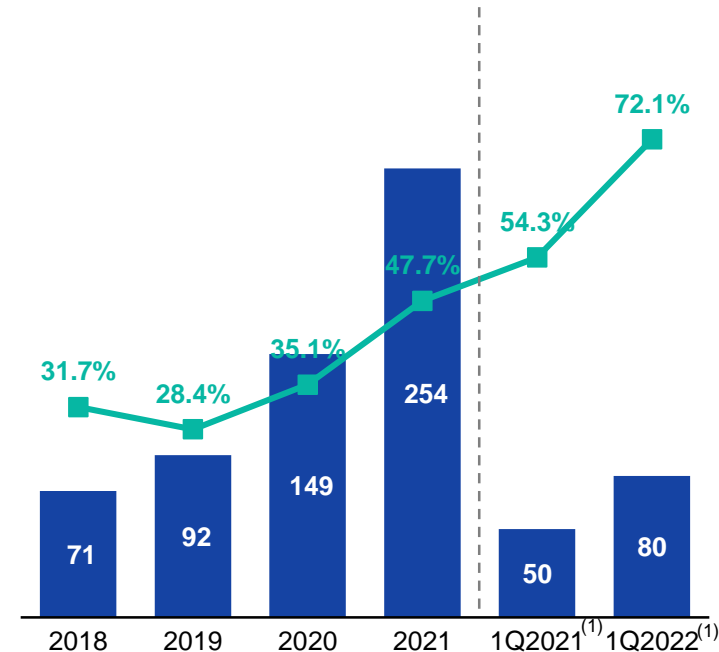
## Administrative expenses

(RMB million)



## R&D expenses

(RMB million)



■ Selling expenses ■ Percentage of total revenue

■ Administrative expenses ■ Percentage of total revenue

■ R&D expense ■ Percentage of total revenue

Note:  
(1) Unaudited financial numbers

# 1Q 2022 Financial Highlights

(in RMB million)	First Quarter		
	Q1 2022	Q1 2021	Y/Y Change
Revenue	110.3	92.1	19.8%
Diagnosis & monitoring - LDT	81.5	71.8	13.5%
Diagnosis & monitoring - IVD	18.0	15.3	18.1%
Development services	10.8	5.0	117.2%
Gross margin	55.7%	59.3%	(360bps)
Selling expenses (% of rev)	82.3%	64.8%	1750bps
R&D expenses (% of rev)	72.1%	54.3%	1780bps
Admin expenses (% of rev)	45.5%	48.4%	(290bps)
Operating loss	(179.9)	(109.0)	-
Net loss	(174.9)	(115.0)	-
Non-IFRS loss <sup>1</sup>	(163.6)	(105.8)	-

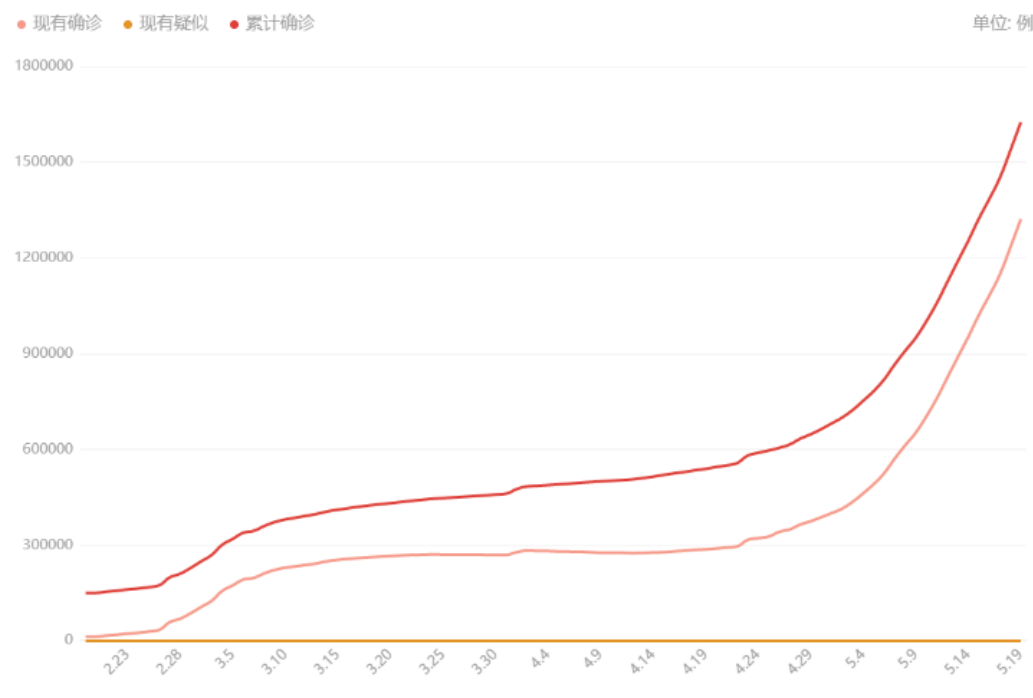
As of March 31, 2022, cash and cash equivalents, restricted cash and current financial assets at fair value through profit or loss were RMB559.1 million

1. Non-IFRS loss represents net results excluding share-based expenses, fair value change and other loss of financial instruments with preferred rights.

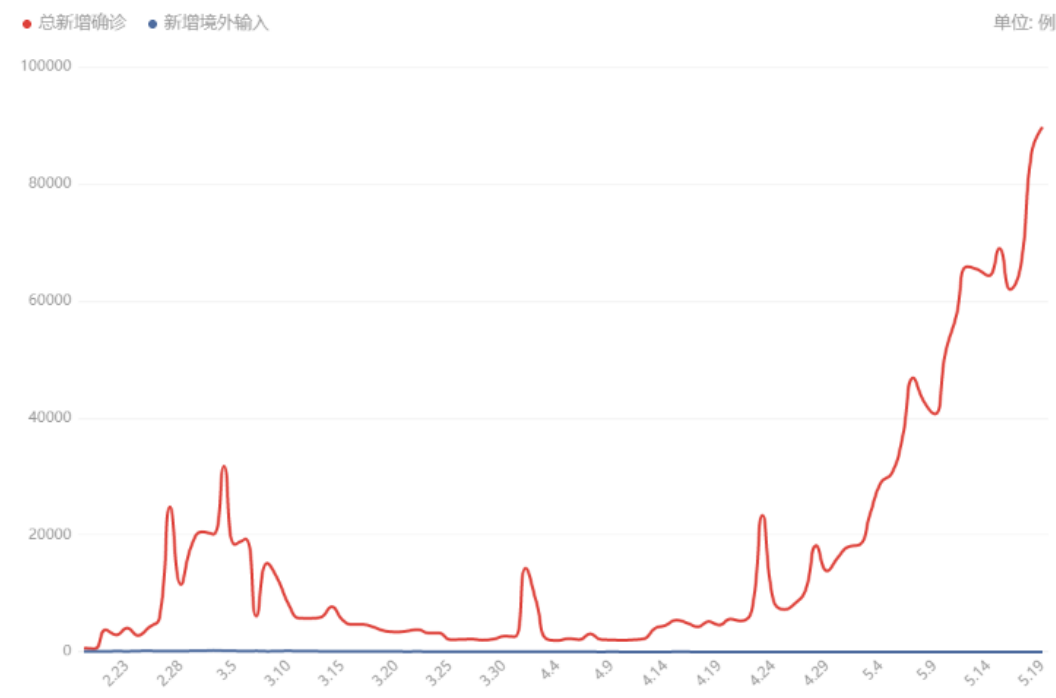


- In first quarter of 2022, Covid-19 situation in China worsened and caused multiple regions' lockdowns
- Starting in March, Shanghai started its most extensive, large-scale lockdown in 2 years. Beijing also has ongoing spread.
- We had baked in conservative assumptions when we provided financial guidance in March. We continue to project full year 2022 revenue to be around RMB 585-638 million, representing 10-20% growth over 2021

全国 现有确诊/疑似/累计确诊 趋势

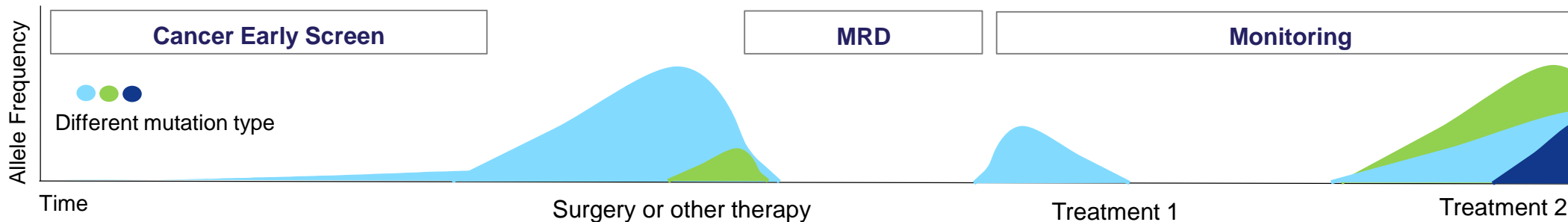


全国 总新增确诊/新增境外输入确诊 趋势

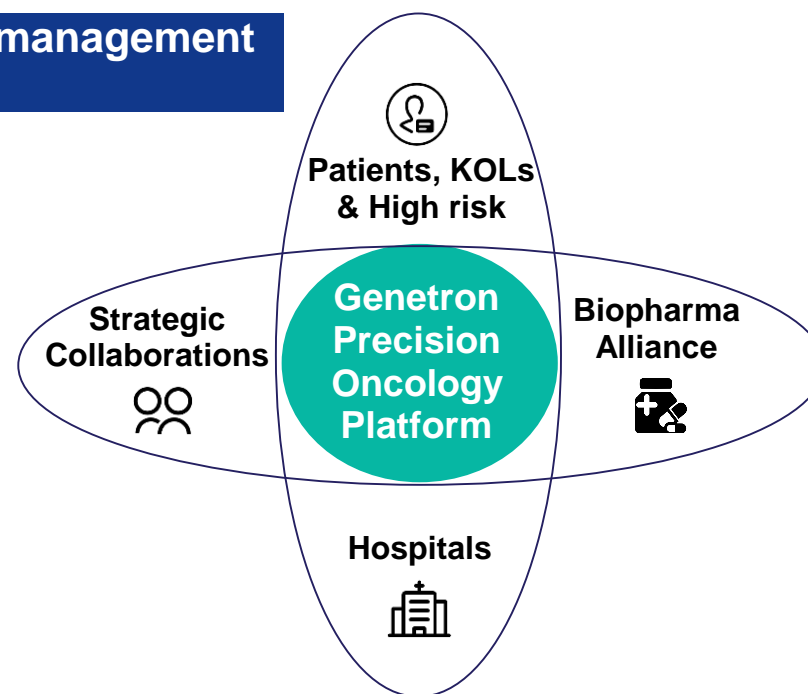
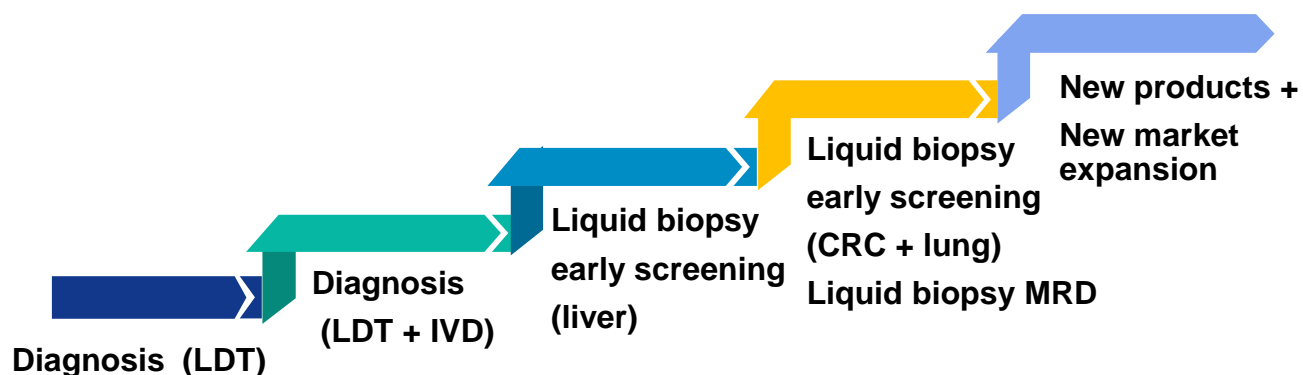


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# Become A Prominent Player in Liquid Biopsy



**Develop liquid biopsy-based solutions across the full-cycle cancer management**  
**Continue to ramp up our commercialization efforts**



## Focused on Transforming the Lifecycle Management of Cancer

### Early Screening

2021:

- ✓ Data readout for large-scale HCC<sup>2</sup> prospective clinical trial
- ✓ HCCscan registrational trial initiated
- ✓ Data readout for CRC<sup>3</sup>

2022:

- HCCscreen registrational trial initiation
- CRC data publication

2023-2024:

- HCCscan and HCCscreen IVD approvals

### MRD<sup>1</sup> Detection

2021:

- ✓ Seq-MRD pilot launch for hematological tumor MRD<sup>2</sup>

2022:

- ✓ Seq-MRD full launch with Fosun
- ✓ Seq-MRD received CE mark
- ✓ Data publication for solid tumor MRD
- Complete product development for solid tumor MRD assay with AZ and commercial launch

### Medication Guidance

2021:

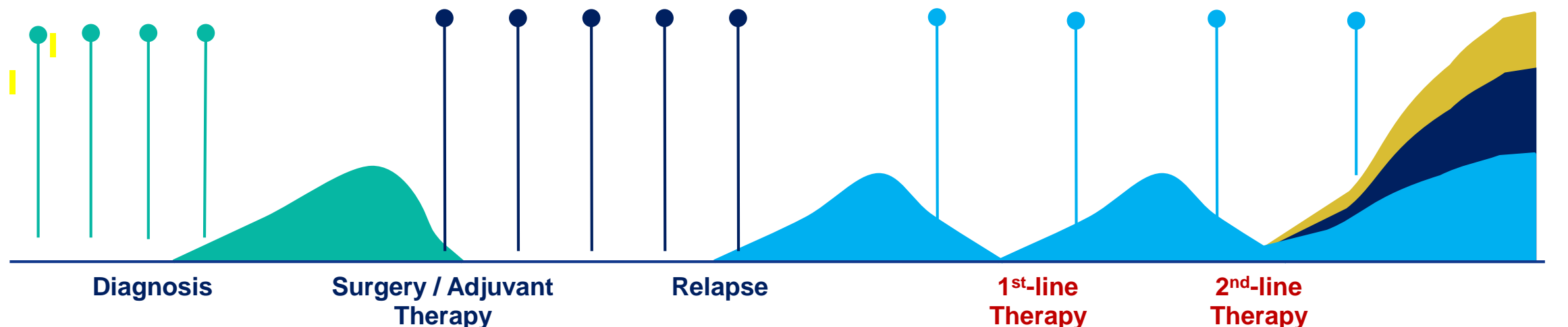
- ✓ OncoPan Scan received CE mark

2022:

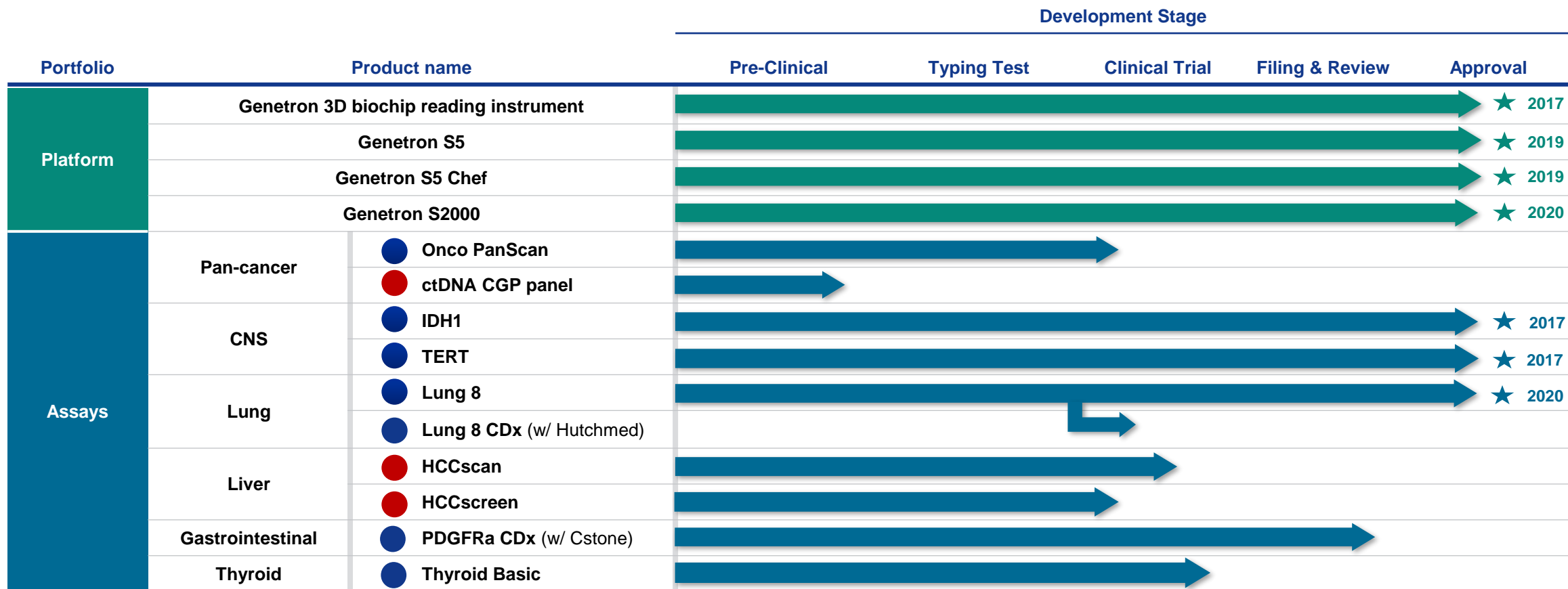
- ✓ FusionScan Plus received CE mark
- Onco PanScan large-panel registrational trial initiation
- Avapritinib CDx kit registration in priority review
- Thyroid assay registrational trial completion
- Next generation liquid biopsy panel launch

2023:

- Thyroid assay IVD approval



1. Minimal residual disease 2. Hepatocellular carcinoma 3. Colorectal cancer



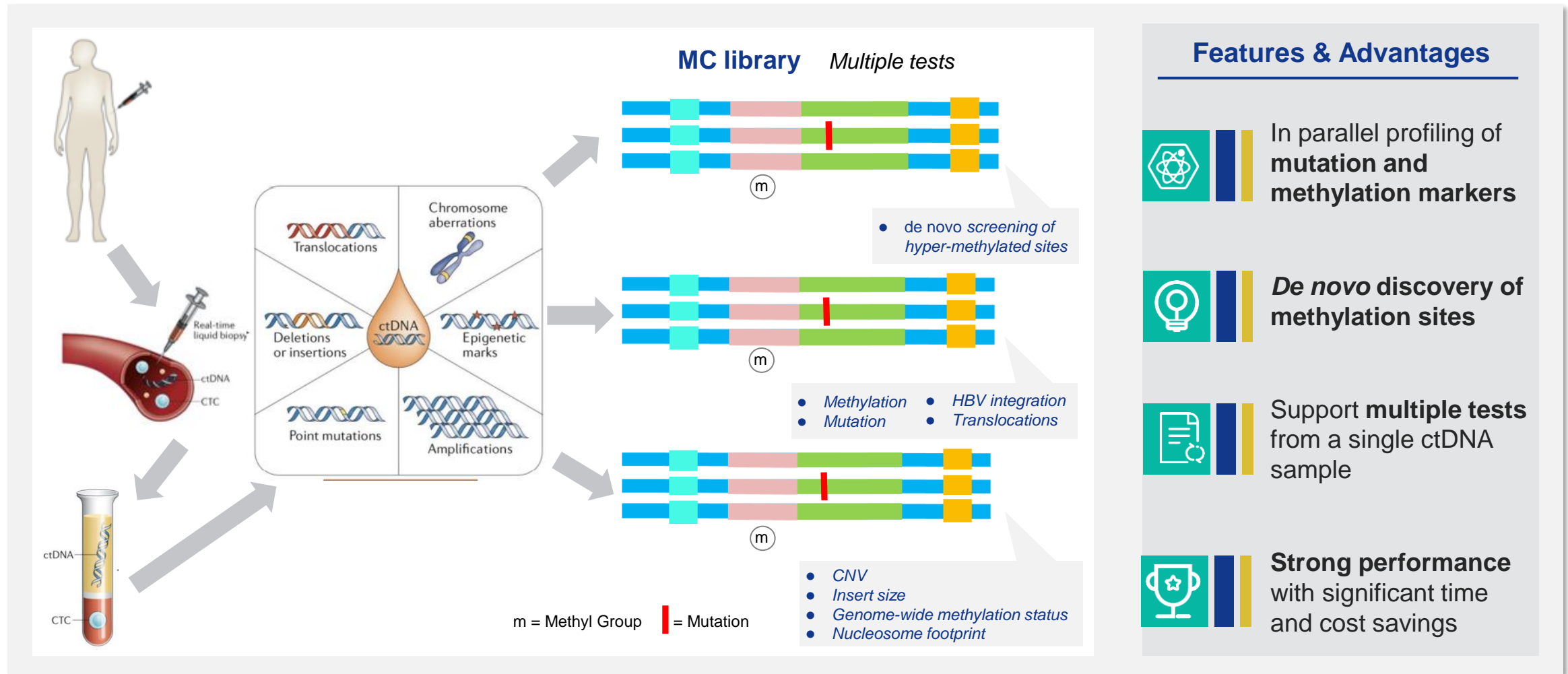
● Tissue biopsy    ● Liquid biopsy    ★ / ★ Approved by NMPA

\* Including software



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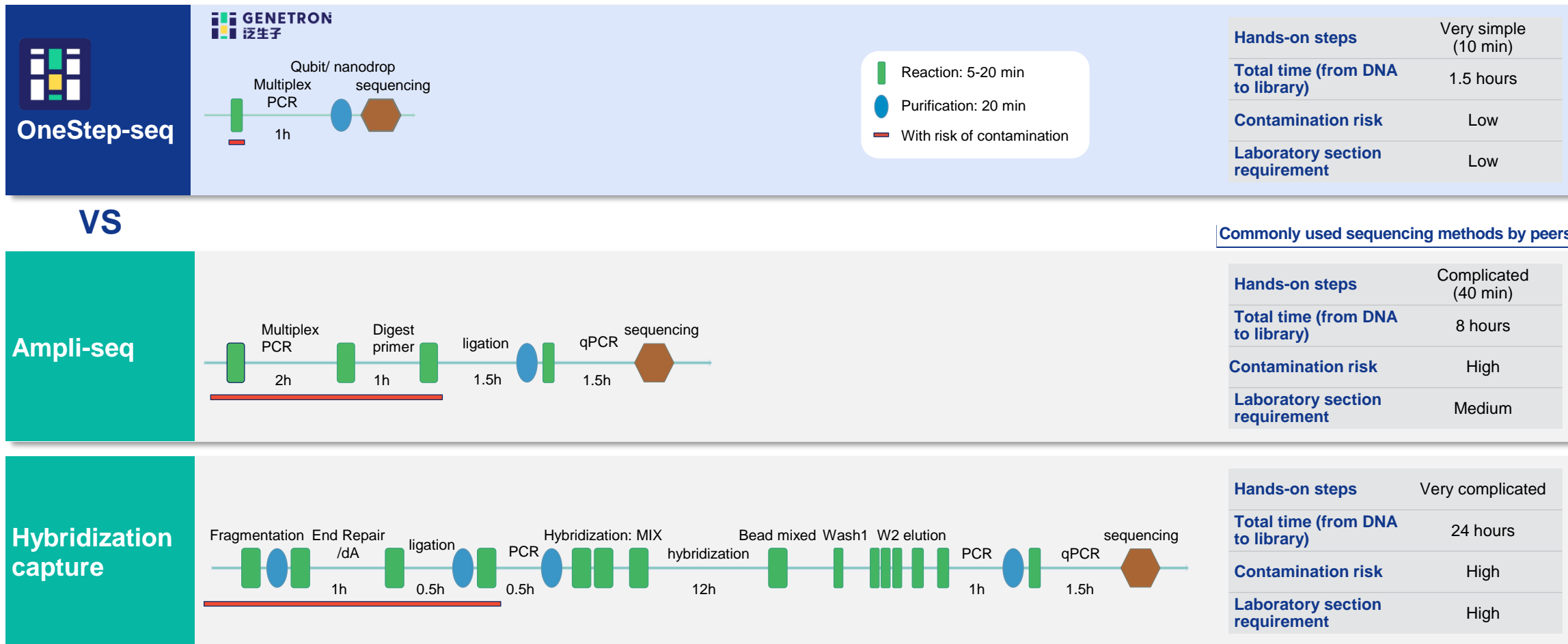


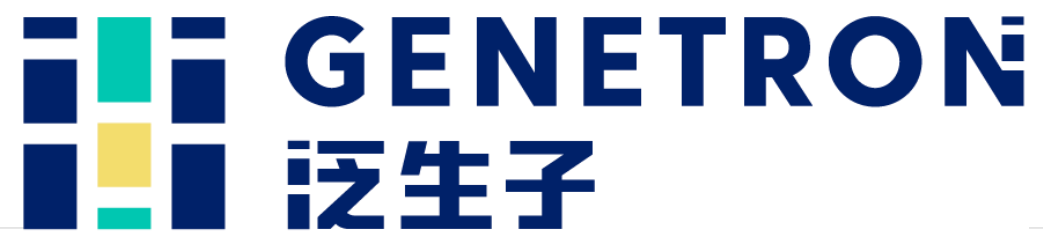


Source: Pantel et al., Nat Rev Clin Oncol, 2019

# Proprietary One-Step Seq Method Presents Significant Advantage For Hospitals in China

## Genetron One-Step Seq vs Amplicon / Hybridization based methods





ANSWERS FOR CANCER