

# **Genetron Holdings Limited**

(Nasdaq: GTH)

3Q 2021 Financial Results

November 2021





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# **Leading Precision Oncology Company in China**



## **Diagnosis & Monitoring (TAM)**

LDT + IVD

**Biopharma Services** 

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

Biotech Industry: \$0.5B<sup>1</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 每早库药 High growth Chinese biotech industry

#1 Ranking: 47 total biopharma partners

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

#### **Early Screening (TAM)**

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

#### HCCscreen<sup>™</sup> –

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

#### HCCscan<sup>™</sup> –

PCR-based assay expands market opportunity leveraging existing customer capabilities

Multi-cancer development with innovative technology in liquid biopsy

Three Proprietary Technology Platforms as foundation: One-step Seq, Mutation Capsules, FusionScan

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





- Recent Events & Business Updates
- 3Q2021 Financials
- Milestones and Growth Strategy
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# 3Q 2021 & Recent Events Recap



## Revenue growth with momentum across all major segments



- Total revenue RMB 152.5 million for 3Q2021, 36.2% y/y revenue growth.
- Gross margin improved to 69.0% vs 62.2% in 3Q2020
- LDT revenue increased by 30.2% y/y to RMB 93.0 million
- IVD revenue increased by 70.5% y/y to RMB 51.3 million

#### Early-screening business with first-mover advantage



- Broadened HCC early screening strategy GTH projects 2023 NMPA approvals for both assays
  - Initiated HCCscan<sup>TM</sup> trial (PCR assay) targeting 9 clinical sites with 5,000 patients
  - HCCscreen<sup>TM</sup> trial (NGS assay) to begin enrollment in the next few months
- Clinical results of early liver cancer screening product HCCscreen<sup>™</sup>, were included in expert consensus and the October 2021 publication of Chinese Journal of Hepatology
- CRC early screening (blood-based) preliminary case control data with >91% sensitivity and 95% specificity

#### MRD Partnership with leading biopharma companies



- Formed a co-development agreement with AstraZeneca R&D China for personalized MRD tests for solid tumors
- Solid tumor MRD data through publications by 1H22
- Entered into an exclusive agreement with Fosun Pharma to commercialize Seq-MRD® for blood cancers in China

#### Diagnosis and biopharma segments progressed well



- Obtained CE Mark for Onco PanScan<sup>TM</sup>, the Company's large panel product that covers over 800 genes
- Established partnerships with NeoGenomics to drive global oncology drug R&D and development
- Established partnerships with IMPACT Therapeutics to development of a synthetic lethal product pipeline

# MRD Business Update



#### **Solid Tumor MRD**

Enabled by proprietary Mutation Capsule platform



#### To develop a world-class tumor-informed MRD product

- Collaboration with AstraZeneca for the joint development of NGS-based tumorinformed MRD tests for various solid tumor types in China
- 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

#### **Seq-MRD®** for Hematologic Cancer

- One-step Seq + fully automated bioinformatics solutions
- Tested with thousands of ALL, MM, and CLL patients





#### **Initiated Commercialization in China**

- 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





Trend of CDx demand is becoming stronger resulting from NMPA's increasing focus on genomic testing for innovative targeted and immunotherapies in China



Strategic partnerships with 47 leading global and China biopharma companies

#### Global clinical drug trials and companion diagnostics development

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



Note: Partner number as of September 30, 2021

# Onco PanScan<sup>TM</sup> – Comprehensive Genomic Profiling Panel





- Comprehensive and evolving coverage of genes
- **High level of precision**
- Lower sample volume requirements

#### **Comprehensive Biomarkers Coverage**

- Detects SNVs, InDels, fusion, copy number variants ("CNVs") and the key immunotherapy biomarkers
- Covers over 125 genes with CDx biomarkers as listed in WHO, NCCN) European Society for Medical Oncology ("ESMO") and other treatment guidelines

#### **New Commercialization Opportunity**

Onco PanScan™ received CE Mark approval permitting commercialization in the EU



# Approach to HCC Early Detection Registration Trials





- PCR-based assay leverages the existing, broad and growing equipment infrastructure driven by government policies and recent insurance programs
- Increases accessibility and potential market penetration
- Multi-methylation marker assay
- 9-sites clinical trials, initiated patient enrollment
- Trial design: HCCscan<sup>TM</sup> vs. HCCscan<sup>TM</sup> + ultrasound vs. ultrasound + AFP in 5,000 patients



- NGS-based
- Multi-omics
- Previous clinical results and technology findings well recognized by expert consensus
- 4-5 sites clinical trials expected to be initiated in 1H2022
- Trial design: HCCscreen<sup>TM</sup> vs. ultrasound + AFP in 5,000 patients

# **Blood-based CRC Early Screening**





- A blood-based assay profiling multi-omics biomarkers including mutation, methylation, copy number variations etc. from cfDNA
- The algorithm was trained in a retrospective cohort of 100 cases and 100 controls, and validated in an independent cohort in same size.
- The assay showed >91% sensitivity with the specificity of 95%.
- Full details from this cohort planned to be released through publication in 2022

# HCCscreen™ – Leading Player in Liver Cancer Early Screening GENETRON⊞EEF

## HCCscreen<sup>™</sup> Investigational Study (HIT): Large-scale Prospective Study of 1,615 HBsAg+ patients reported in March 2021

Superior sensitivity and comparable specificity

vs. ultrasound + AFP: 71% sensitivity, 95% specificity

88% Sensitivity 93%

40.9%

99.3%

**Specificity** 

**PPV** 

**NPV** 

PPV: Positive Predictive Value NPV: Negative Predictive Value HCC: hepatocellular carcinoma

Excellent sensitivity in detecting early-stage HCC						
Sensitivity	<b>85%</b>	96%	88%			
Tumor size	<3cm	3-5cm	>5cm			
Very Early Stage	Early Stage	Mid Stag	e Late Stage			
Tumor size	e <3cm		Distant metastasis			
5-year survival rate 80%-90%		Hig	High Mortality Rate			
Golden Treatment Period		Detection Range with Traditional Method				



- The clinical results and technology findings of HCCscreen<sup>™</sup> were included in *Chinese Journal of Hepatology* Oct 2021
- Well-recognized by expert consensus





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# 3Q 2021 Revenue



61%

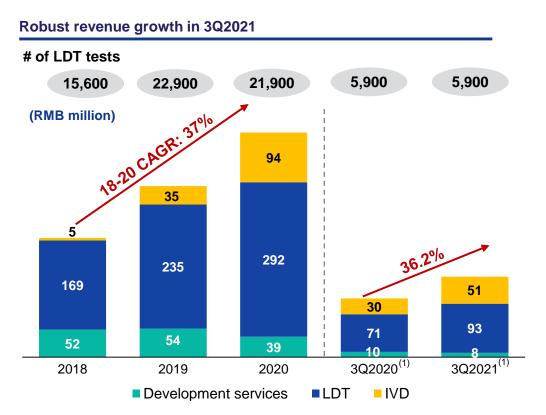
3Q2021 (1)

9%

3Q2020<sup>(1)</sup>

#### **3Q2021** revenue growth drivers:

- Sales of LDT services included sales of our early screening test, HCCscreen<sup>TM</sup>
- Increased IVD revenue was driven by increasing sales of Genetron S5 instrument and 8-gene Lung Cancer Assay (Tissue)
- Development services: Continued strategic shift to higher margin biopharma services



# 75% 72% 69% 64%

9%

2020

■ Development services ■ LDT ■ IVD

IVD revenue as a percentage of total revenue increased in 3Q2021

Note:

Unaudited financial numbers

23%

2018

17%

2019

# 7

# Winning the China Hospital Market



#### Starting from LDT then evolving into "LDT + IVD"

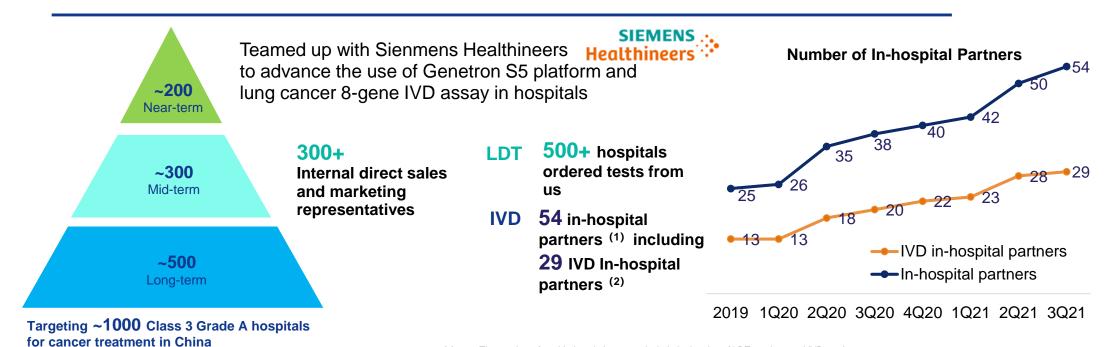
#### Laboratory developed test (LDT)

- 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



The number of total in-hospital partners include both sales of LDT services and IVD products.

<sup>(2)</sup> By September 30, 2021

# 3Q 2021 Gross Margin



#### ANSWERS FOR CANCER

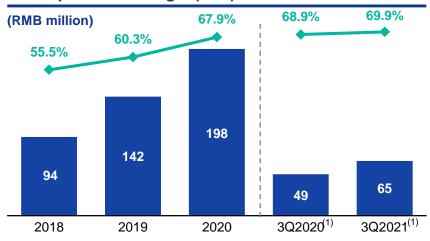
#### **Gross profit and margin**



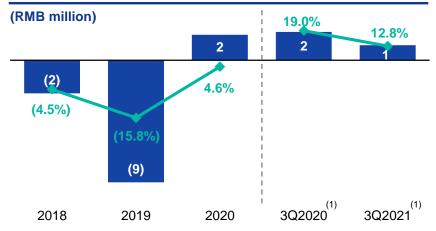
#### **Gross profit and margin (IVD)**



#### **Gross profit and margin (LDT)**

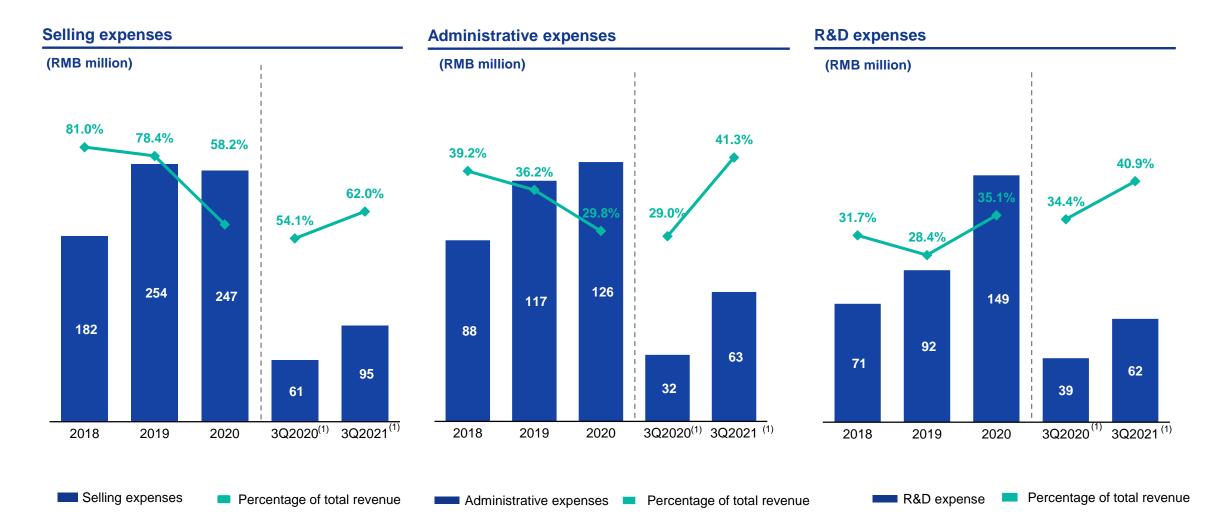


#### **Gross profit and margin (Development services)**



# 3Q 2021 Operating expenses





Note:

Unaudited financial numbers



# 3Q 2021 Financial Highlights



#### **Third Quarter**

(in RMB million)	Q3 2021	Q3 2020	Y/Y Change
Revenue	152.5	112.0	36.2%
Diagnosis & monitoring - LDT	93.0	71.4	30.2%
Diagnosis & monitoring - IVD	51.3	30.1	70.5%
Development services	8.2	10.4	(21.4%)
Gross margin	69.0%	62.2%	680bps
Selling expenses (% of rev)	62.0%	54.1%	790bps
R&D expenses (% of rev)	40.9%	34.4%	640bps
Admin expenses (% of rev)	41.3%	29.0%	1230bps
Operating loss	(124.8)	(59.2)	-
Net loss	(130.1)	(48.0)	-
Non-IFRS loss <sup>1</sup>	(109.9)	(43.7)	-

As of September 30, 2021, cash and cash equivalents, restricted cash and current financial assets at fair value through profit or loss were RMB1,005.3 million

<sup>1.</sup> Non-IFRS loss represents net results excluding share-based expenses, fair value change and other loss of financial instruments with preferred rights. Please refer to appendix for the reconciliation of non-IFRS loss for the year/period to net loss for the year/period

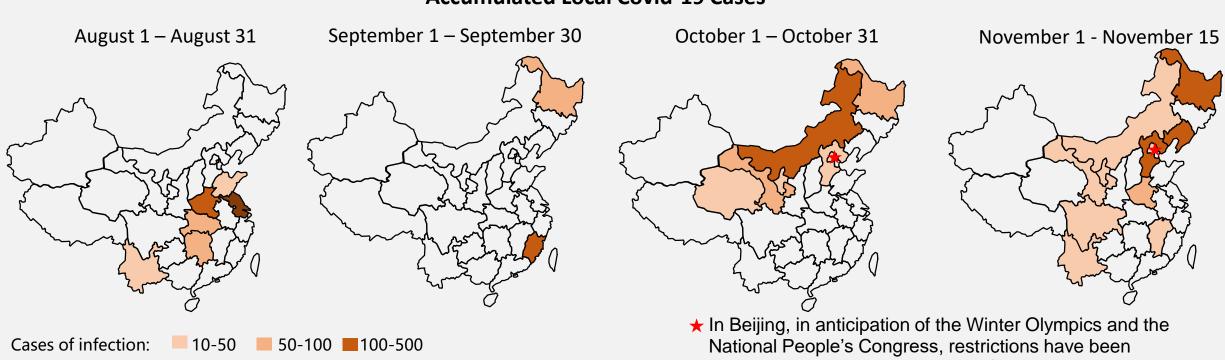


# Covid-19 Situation in China – 3Q21 and 4Q21



## Covid-19 resurgence in China intensified since October; LDT business was impacted significantly

#### **Accumulated Local Covid-19 Cases**

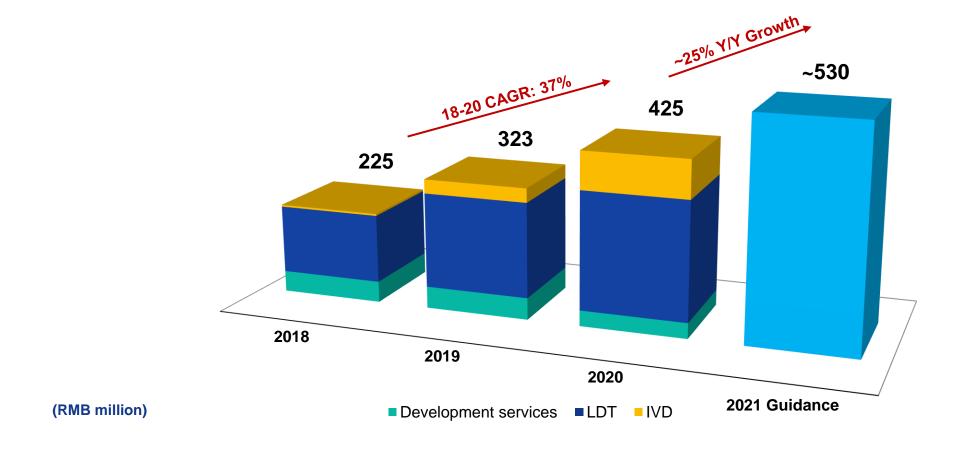


Source: National Health Commission

particularly severe and this level of high alert is likely to stay.







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ctDNA clone

detectable in

#### **Focused on Transforming the Lifecycle Management of Cancer**

## **Early Screening**

#### 2021:

- Data readout for large-scale prospective liver cancer screening trial
- HCCscan registrational trial initiated
- Data readout for colorectal cancer

#### 2022:

- HCCscreen registrational trial initiation
- **CRC** publication
- Completion of HCCscan and HCCscreen registrational trials by YE

#### 2023:

**HCCscan** and **HCCscreen** approvals

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

#### 2021:

Product launch for hematological tumor MRD<sup>1</sup>

#### 2022:

**Surgery / Adjuvant** 

**Therapy** 

Data publication for solid tumor MRD in 1H

#### **Medication Guidance**

#### 2021:

OncoPan Scan received CE mark

1st-line

**Therapy** 

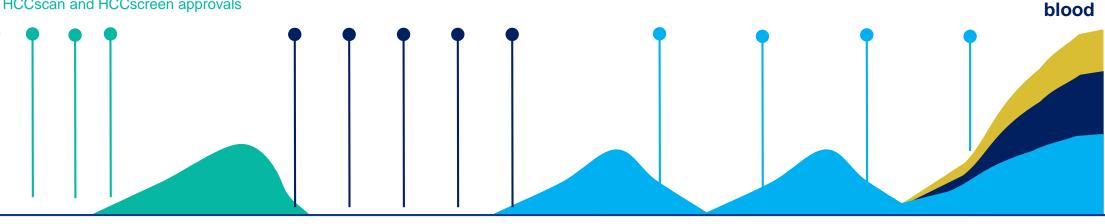
Avapritinib companion diagnostic kit approval

#### 2022:

Onco PanScan large-panel registrational trial initiation in Q1

2<sup>nd</sup>-line

**Therapy** 



**Diagnosis** 

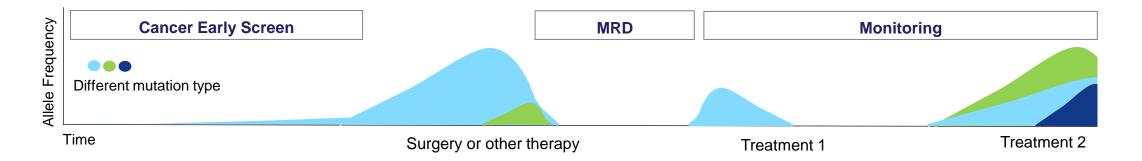
Relapse

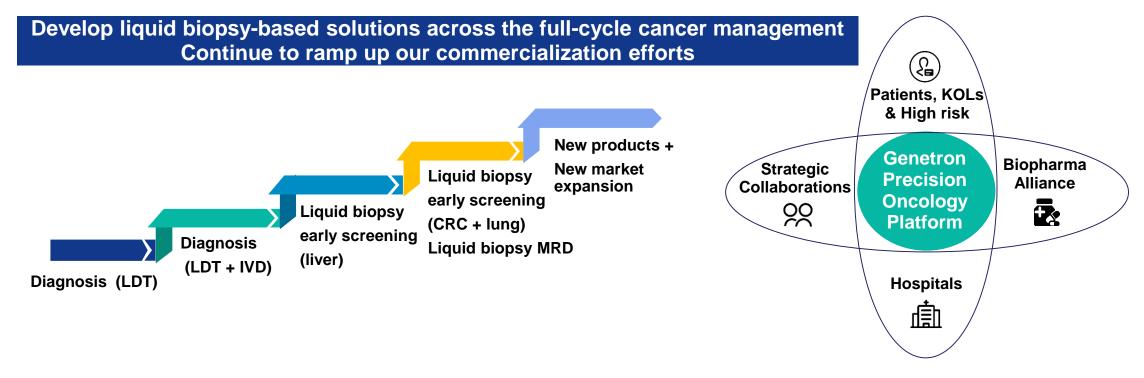
Minimal residual disease



# **Become A Prominent Player in Liquid Biopsy**







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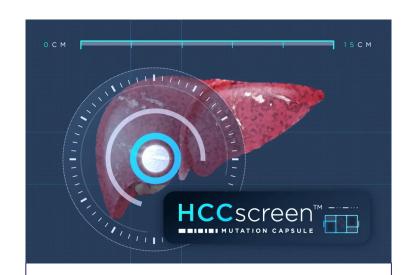


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# First Mover Advantage in Early Screening Commercialization



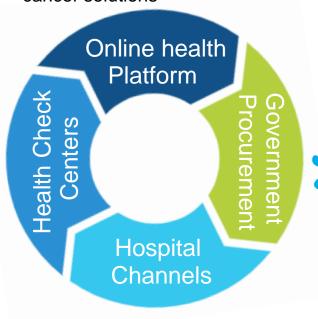
ANSWERS FOR CANCER



- Powered by Genetron's innovative and proprietary Mutation Capsule Technology
- Received **U.S. FDA** breakthrough designation – expands geographical reach

# JDH,京东健康

Aim to jointly create an internet innovation model for full-cycle cancer solutions





Collaborated with local governments for public health initiatives Wuxi Huishan in Jiangsu (江苏省无锡市惠山区) Bijie Dafang in Guizhou (贵州省毕节市大方县)

## *i*Kang 爱康

Service available at 100+ iKang medical exam centers nationwide



Partnership with CTTQ, a subsidiary of SBP (1177.HK), which has great access to China's hepatitis hospital market

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





**Lung Cancer 8-Gene Kit** 



**Genetron S5** 



**Accurate Testing** 

**Speedy Process** 

High sequencing consistency, repetition rate and accuracy
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%	

<sup>1.</sup> Oncologist. 2019 Nov;24(11):e1070-e1081.

#### **Target at China Hospital Market**

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

#### **New Commercialization Opportunity**

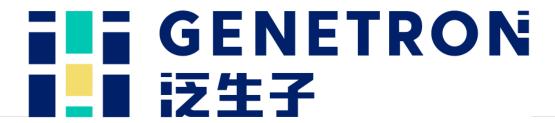
Received **CE Mark** for 8-gene Lung Cancer Assay, the second regulatory milestone for this assay



# Unaudited NON-IFRS Financial Measures



	For the three months ended,		
	September 30, 2020	September 30, 2021	
	RMB'000	RMB'000	
Loss for the period	(47,998)	(130,147)	
Adjustments:			
Share-based compensation	4,268	20,246	
Non-IFRS Loss	(43,730)	(109,901)	
Attributable to:			
Owners of the Company	(43,730)	(108,728)	
Non-controlling interests	<u> </u>	(1,173)	



**ANSWERS FOR CANCER**