# Burning Rock Biotech Limited
## 3Q20 Updates

Nasdaq listed since Jun 2020, BNR US Equity

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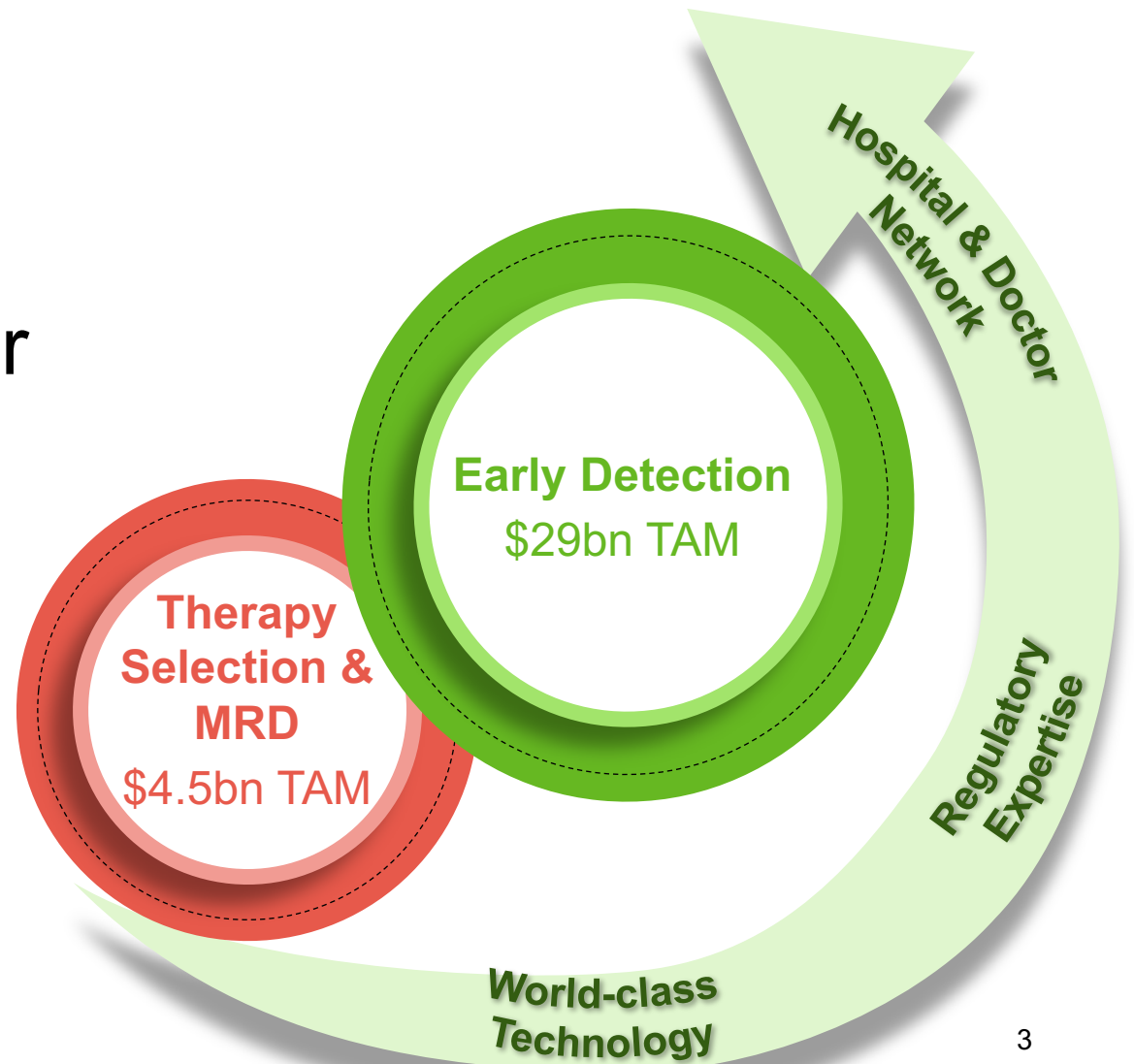
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China's **molecular diagnostics** leader for **precision oncology**

**Early Detection**
$29bn TAM

**Therapy Selection & MRD**
$4.5bn TAM

Hospital & Doctor Network

Regulatory Expertise

World-class Technology

# Our focus

## Therapy Selection

- Expand leadership in the China market, based on product performance and quality, for both tissue- and liquid-based NGS testing

- Enable higher NGS testing penetration through kit-based in-hospital channel, complementing existing central-lab based testing

## Early Detection

- Be at the forefront of global R&D on blood-based pan-cancer early detection, through in-house R&D and clinical collaborations with top physicians and hospitals in China
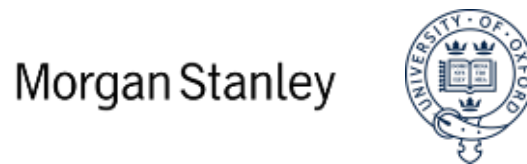
# Our team

**Yusheng Han**
Founder, Chairman, CEO

北极光创投
northern light
VENTURE CAPITAL

BioTek
A part of Agilent

Columbia Business School
AT THE VERY CENTER OF BUSINESS™

**Shannon Shaokun Chuai, Ph.D.**
Director, Chief Operating Officer

NOVARTIS     Penn

**Joe Zhihong Zhang, Ph.D.**
Chief Technology Officer

illumina     hhmi
Howard Hughes
Medical Institute     Duke
UNIVERSITY

**Leo Li**
Director, Chief Financial Officer

Morgan Stanley     UNIVERSITY OF OXFORD

**Hao Liu**
Chief Medical Officer

NOVARTIS     Pfizer

# Today's topics

**Early Detection**

- Product roadmap update

- 6-cancer test validation data released at ESMO Asia Virtual Congress 2020

**Therapy Selection**

- MagnisBR analytical validation data released at Association for Molecular Pathology (AMP) Annual Meeting

- Myriad myChoice HRD test in-licensing

**Numbers**

- 3Q20 operating metrics

- 3Q20 financials

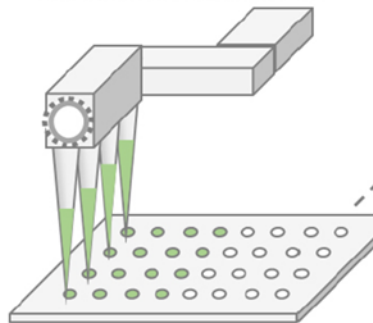# Burning Rock early detection technology – ELSA-Seq

## R&D started in 2016
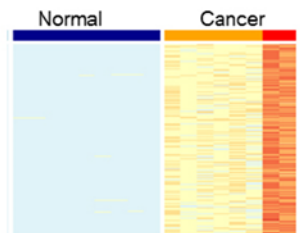## Combination of targeted deep methylation sequencing and machine learning
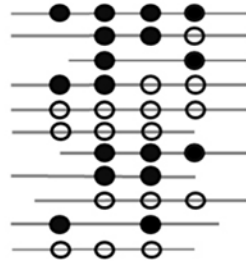


(A) Sample preparation
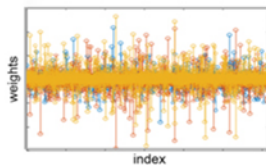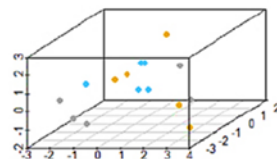
(B) Automated whole-methylome amplification

(C) Deep sequencing of cancer-associated markers

Normal    Cancer

(D) Pattern recognition & noise suppression

(E) Machine learning for sparse matrices

weights

index

Technology Highlights:

- Single-stranded library prep starts as low as 1ng cfDNA

- Bisulfite conversion or enzymatic conversion compatible

- Intelligent probe design to maintain the methylation level fidelity

- Multiple noise reduction and signal corrections before machine-learning model building

# Early detection product development roadmap

## Latest progress – expanded from 3 to 6 cancer types with improved specificity

**Proof-of-concept**
Single-cancer
2019

- Completed. Results released at AACR 2019
- Lung cancer, proof of concept on assay and bioinformatics methodology
- Manuscript on methodology under peer review
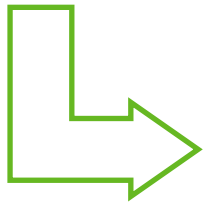
**Proof-of-concept**
3-cancer
Jan 2020

- Completed. Results released at AACR Special Conference on Liquid Biopsy, Jan 2020
- Lung, CRC, HCC
- 95.1% specificity (95% CI 91.2-97.4) and 80.8% sensitivity (95% CI 77.0-84.1)[1]
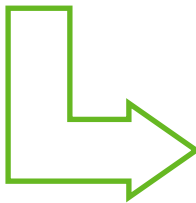
**Prototype**
6-cancer
Nov 2020

- Completed. Results released at ESMO Asia, 20th Nov 2020
- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal
- 98.3% specificity (95% CI 95.8-99.4) and 80.6% sensitivity (95% CI 76.0-84.6)[2]
- Tissue-of-origin (TOO) result in 98.6% cases; among those 81.0% (95%CI: 77.2-84.3%) were correct
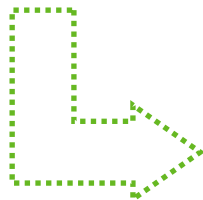
**Commercial**
9-cancer
Ongoing

- Assay under development; training and validation to follow
- Lung, CRC, HCC, Ovarian, Pancreatic, Esophageal, Gastric, Cholangio, Head & neck

Notes:
[1] Training and validation cohorts combined, 490 cancer samples, 226 control samples. Sample size numbers are aggregated, through a series of case-control studies.
[2] Validation cohort, 351 cancer samples, 288 control samples. Sample size numbers are aggregated, through a series of case-control studies.

# Clinical progress

**Marker discovery**
(tissue)

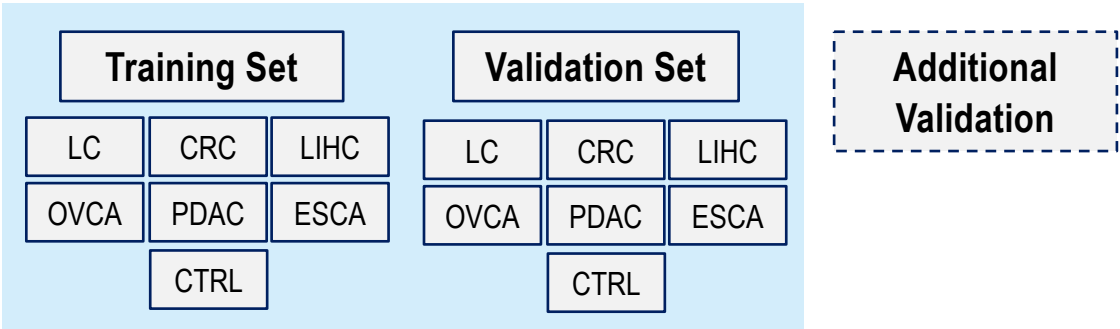| ~5.5 million CpG sites LC/CRC/LIHC/OVCA/PAAD/ESCA | ~450,000 CpG sites TCGA & GEO database |

**Panel validation**
(tissue and blood)

| ~160,000 CpG sites LC/CRC/LIHC/OVCA/PAAD/ESCA/Control |

**Assay validation**
(blood)

**Training Set**

| LC | CRC | LIHC |
| OVCA | PDAC | ESCA |
| | CTRL | |

**Validation Set**

| LC | CRC | LIHC |
| OVCA | PDAC | ESCA |
| | CTRL | |

**Additional Validation**

# Overview of training and validation sets
## Comparable cancer and non-cancer groups

| Training | Control | Cancer | LC | CRC | LIHC | OVCA | PAAD | ESCA |
|---|---|---|---|---|---|---|---|---|
| total | 195 | 274 | 50 | 46 | 48 | 50 | 40 | 40 |
| age, mean+/-SD | 53+/-6 | 57+/-8 | 60+/-6 | 60+/-8 | 55+/-8 | 50+/-8 | 59+/-7 | 57+/-6 |
| age, min/max | 40/72 | 40/75 | 47/74 | 44/75 | 43/72 | 40/73 | 42/71 | 45/70 |
| sex, female, n (%) | 128 (70) | 110 (40) | 16 (32) | 21 (46) | 4 (8) | 50 (100) | 14 (35) | 5 (13) |
| clinical stage, n (%) | | | | | | | | |
| I | | 73 (27) | 20 (40) | 9 (20) | 20 (41) | 5 (10) | 11 (27) | 8 (20) |
| II | | 63 (23) | 14 (28) | 12 (26) | 8 (17) | 5 (10) | 11 (27) | 13 (33) |
| III | | 97 (35) | 7 (14) | 15 (32) | 14 (29) | 37 (74) | 9 (23) | 15 (37) |
| IV | | 41 (15) | 9 (18) | 10 (22) | 6 (13) | 3 (6) | 9 (23) | 4 (10) |

| Validation | Control | Cancer | LC | CRC | LIHC | OVCA | PAAD | ESCA |
|---|---|---|---|---|---|---|---|---|
| total | 288 | 351 | 61 | 57 | 57 | 53 | 59 | 64 |
| age, mean+/-SD | 54+/-6 | 59+/-8 | 62+/-7 | 61+/-9 | 54+/-8 | 54+/-7 | 61+/-9 | 62+/-6 |
| age, min/max | 40/74 | 40/75 | 45/74 | 44/75 | 40/73 | 42/68 | 40/74 | 46/74 |
| sex, female, n (%) | 171 (59) | 146 (42) | 22 (36) | 21 (37) | 9 (16) | 53 (100) | 19 (32) | 22 (34) |
| clinical stage, n (%) | | | | | | | | |
| I | | 83 (23) | 16 (26) | 15 (26) | 15 (26) | 6 (11) | 18 (30) | 13 (20) |
| II | | 87 (25) | 16 (26) | 13 (23) | 14 (25) | 11 (21) | 14 (24) | 19 (30) |
| III | | 94 (27) | 14 (23) | 14 (25) | 15 (26) | 22 (42) | 13 (22) | 16 (25) |
| IV | | 87 (25) | 15 (25) | 15 (26) | 13 (23) | 14 (26) | 14 (24) | 16 (25) |

1.  Similar age distribution between cases and controls, and between training set and validation set

2.  Balanced sample size among different stages and cancer types

Note:
Sample size numbers are aggregated, through a series of case-control studies.

# Our test detects cancers at early stage with high specificity and high sensitivity



Sensitivity

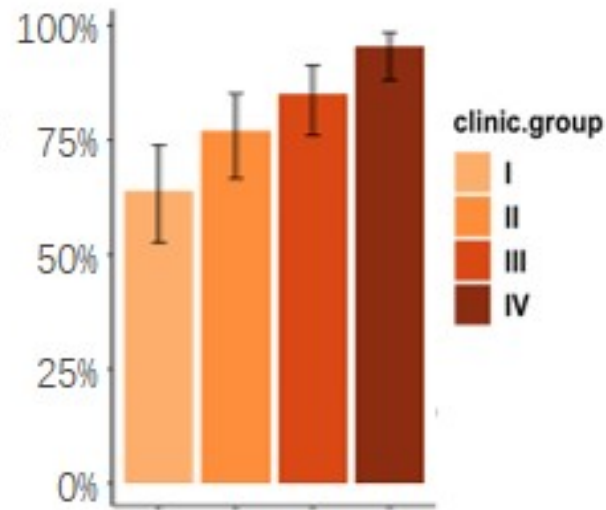Clinical Stages   (# in Training / # in Validation)
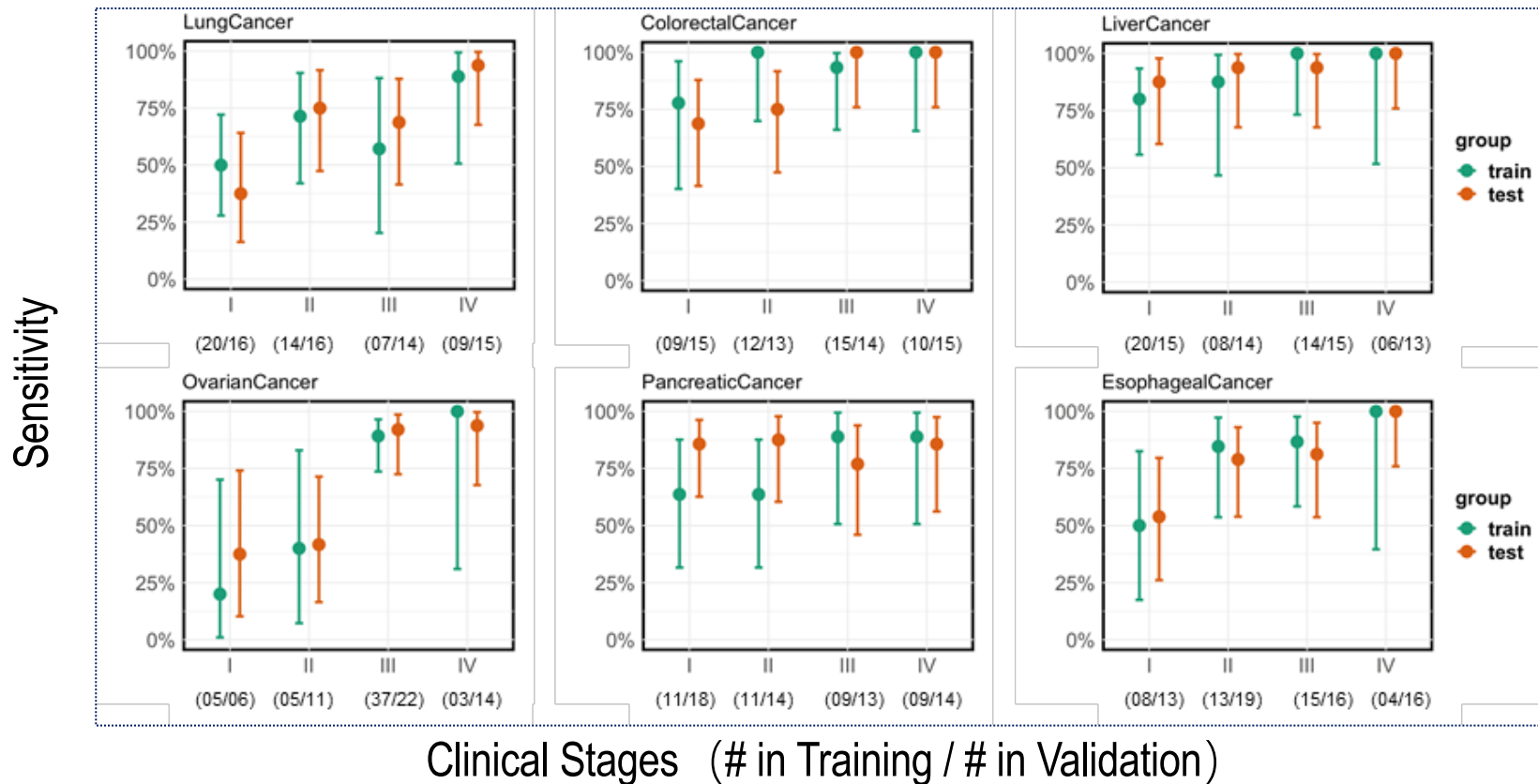
- The specificity was **99.5%** (95%CI: 96.7-100%; training) and **98.3%** (95%CI: 95.8-99.4%; validation).

- The sensitivity was **79.9%** (95%CI: 74.6-84.4%; training) and **80.6%** (95%CI: 76.0-84.4%; validation).

# Our test detects cancers at early stage with high specificity and high sensitivity
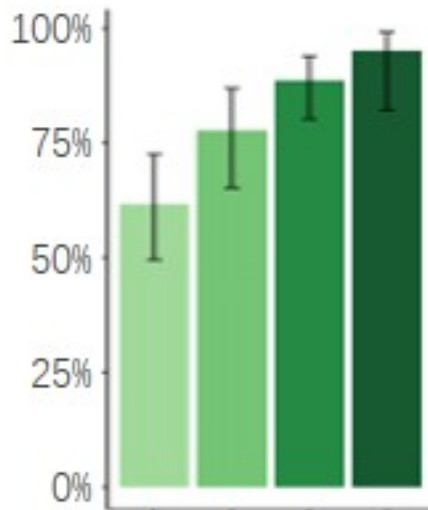


Training

Validation
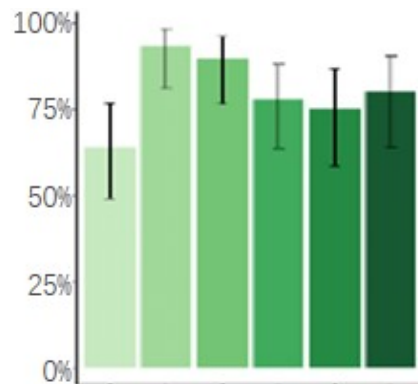
Training
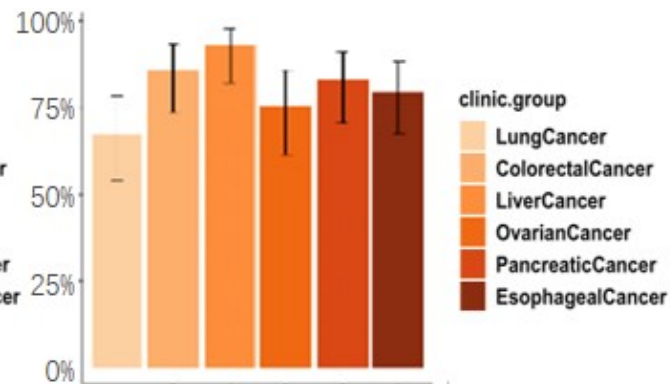
Validation

# Our test predicts the tissue of origin with high accuracy
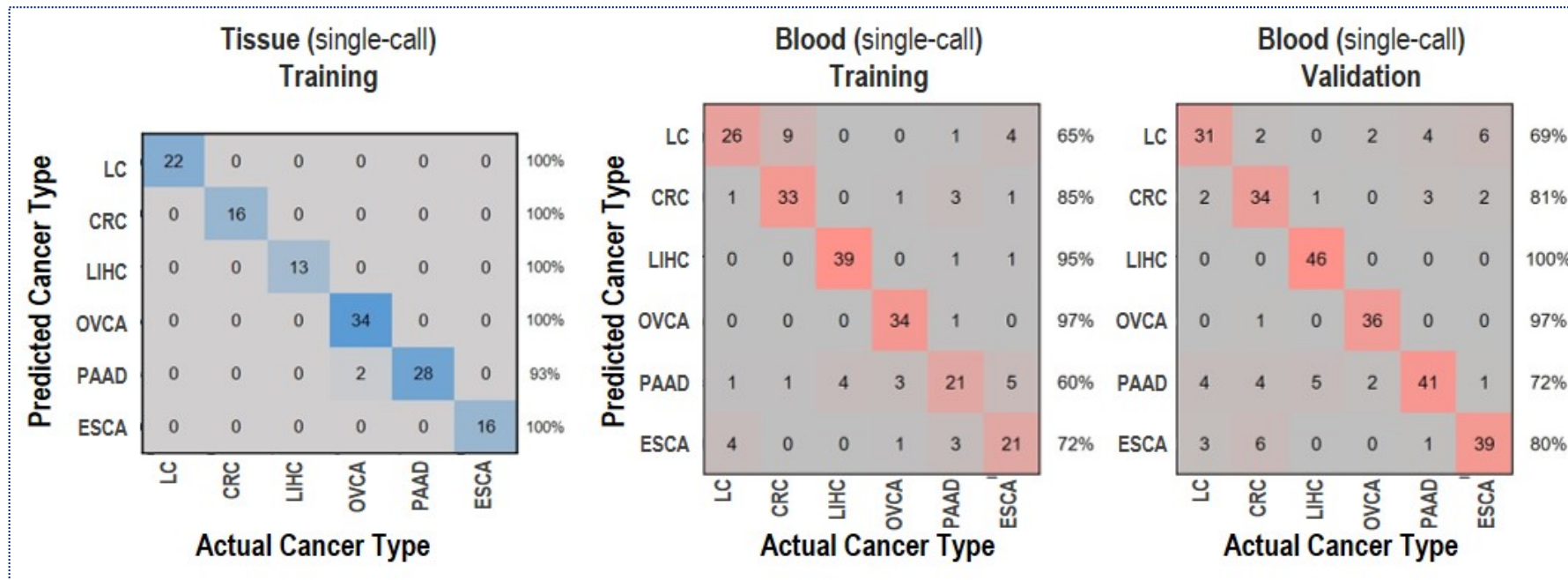


- The classifier was able to distinguish different cancer tissue samples with exceptional accuracy **(129/131).**

- **98.6%** of detected cancer blood samples were assigned an organ-source in both training and validation sets:
  - For single organ calls, the predictive accuracy was **79%** (training) and **82%** (validation);
  - For top-two organ calls, the predictive accuracy was **89%** (training) and **87%** (validation).

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**Numbers**

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# Magnis BR: a turn-key solution for hospitals

**1** Extraction

**2** Library Prep Magnis BR

**3** Sequencing

**4** Bioinformatics

## Current Manual Process

| | Manual | Total |
|---|---|---|
| End Repair | 20min | 1h20min |
| Adapter Ligation & Purification | 30min | 1h20min |
| Pre-Library Amp. & Purification & QC | 40min | 1h20min |
| Hybridization | 30min | 16h |
| Capture & Wash | 40min | 1h40min |
| Post-Library Amp. & Purification | 30min | 1h30min |
| Post-Library QC | 10min | 10min |

| 200min Total Hands-On Time | ~24h Total Assay Time |
|---|---|

## Magnis BR
Co-developed with Agilent; BR proprietary chemistry

| Highly efficient | Fully automated | Integrated system |
|---|---|---|

| Superior QC | 112 samples per week |
|---|---|

## Library Preparation at the Press of a Button

**Fully Automated Process** → **5min Setup Time** → **~9h Total Assay Time**

# Analytical Validation of Magnis BR Assay

## OncoScreen IO Tissue assay
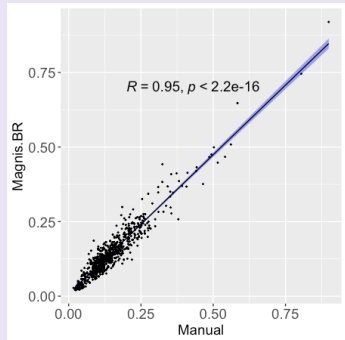


In 16 clinical FFPE samples. The concordance rate for total 717 variants was 98.7%, and 100% for MSI status (Jaccard Index).
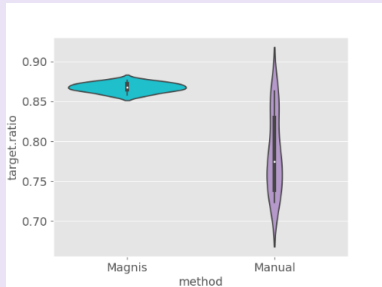


Magnis BR improved the capture on-target ratio by an average of 8% (86% vs 78%).

## OncoCompass Target cfDNA Assay
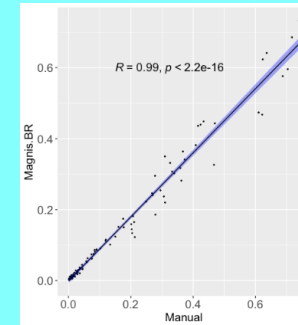


In 34 Clinical cfDNA samples, the concordance rate for total 120 variants VV was 97.5%.

The sensitivity of MSI detection achieved 100% under the tumor cell fraction of 0.25% at median sequencing depth of 15000X.

**Analytical validation performed on our top-selling 520-gene tissue and 168-gene liquid panels**

# Myriad myChoice® HRD test in-licensing



measures a phenotype of genomic instability associated with HRD
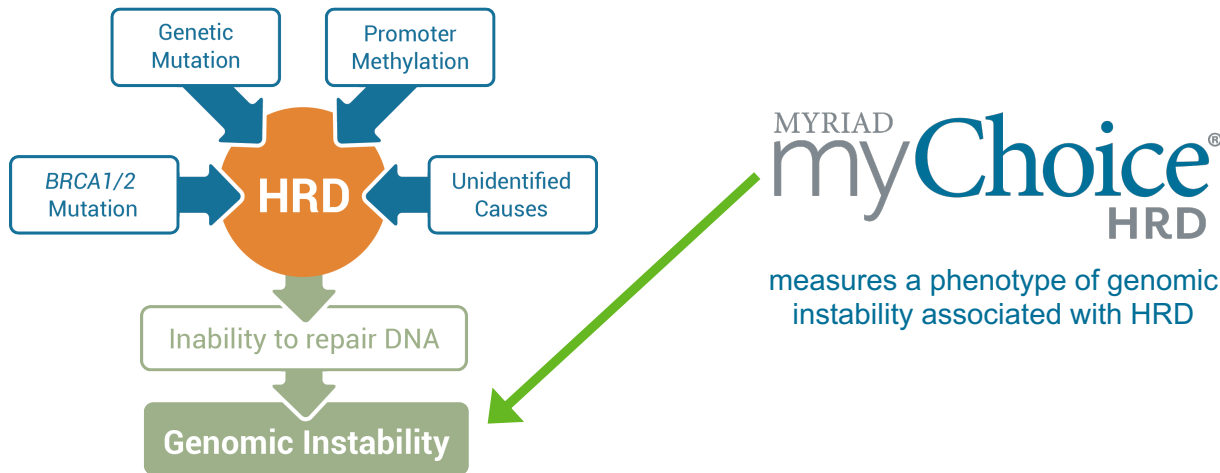
**FDA CDx approval: tBRCAm and/or genomic instability score (GIS) ≥ 42**

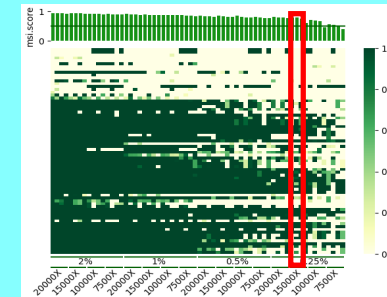| Drug and Cancer | Indication | Trial and Approval Date |
|---|---|---|
| Olaparib (AZ) Ovarian Cancer | First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with Bevacizumab | PAOLA-1, May 8, 2020 |
| Niraparib (GSK) Ovarian Cancer | Advanced HRD-positive ovarian cancer after three or more chemotherapies | QUADRA, Oct 23, 2019 |

*Indication approved in China: Olaparib 1st line maintenance treatment of BRCA-mutated advanced ovarian cancer*

# Myriad myChoice® HRD in-licensing

- Immediately addressable market (on-label use): first-line aOC patients with maintenance therapy: ~10000-15000 annually

- Drugs and cancer types being studied using myChoice® HRD as a companion or exploratory biomarker:

  ✓ Olaparib: HER2- breast cancer

  ✓ Niraparib: ovarian cancer

  ✓ Veliparib: ovarian cancer, pancreatic cancer

  ✓ Talazoparib: triple-negative breast cancer

  ✓ Pamiparib: locally advanced or metastatic solid tumors

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# Operating metrics

|  | **2018** | **2019** | **1Q19** | **2Q19** | **3Q19** | **4Q19** | **1Q20** | **2Q20** | **3Q20** |
|---|---|---|---|---|---|---|---|---|---|
| **Central-lab channel** | | | | | | | | | |
| # of ordering hospitals | 263 | 335 | 249 | 265 | 281 | 304 | 232 | 284 | 289 |
| # of ordering physicians | 1,135 | 1,632 | 984 | 1,059 | 1,155 | 1,222 | 810 | 1,175 | 1,194 |
| # of patients tested[1] | 15,821 | 23,075 | 5,336 | 6,047 | 6,769 | 7,576 | 4,680 | 7,252 | 8,644 |
| *YoY* | *67%* | *46%* | | | | | *-12%* | *20%* | *28%* |
| *QoQ* | | | | | | | | *55%* | *19%* |

**In-hospital channel**



- # of contracted hospitals
- # of pipeline hospitals
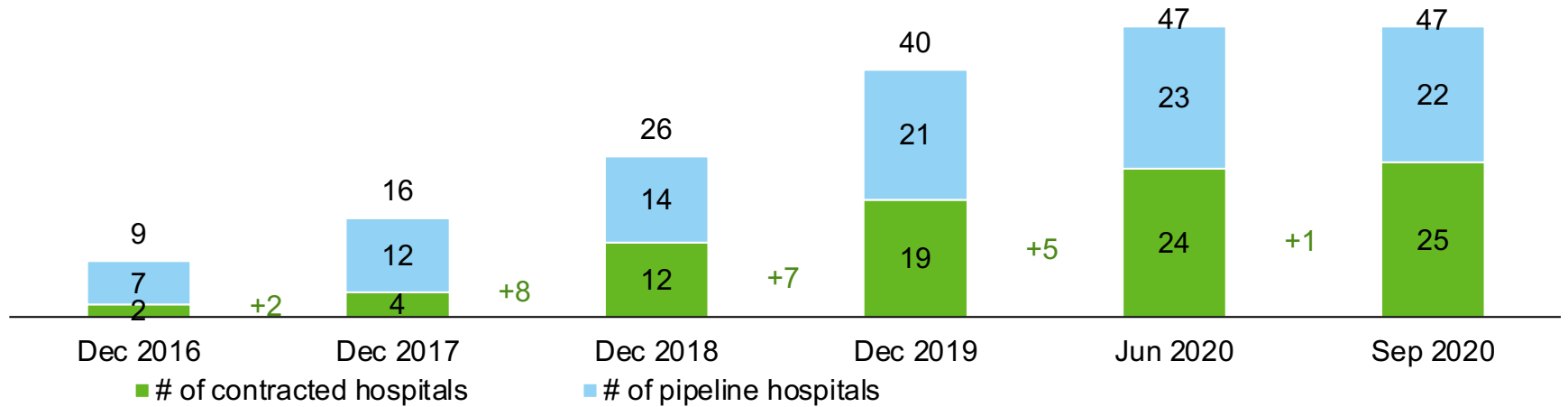
- Magnis BR placed in more than 10 hospitals; Revenue booked for 1 instrument in Jan 2020 during 9M20

Note:
[1] A patient who took multiple tests in different quarters of a given year is counted only once for that year

# Financials

| RMB millions | 2019 | 18 YoY | 19 YoY | 1Q19 | 2Q19 | 3Q19 | 4Q19 | 1Q20 | 2Q20 | 3Q20 | 1Q20 YoY | 2Q20 YoY | 3Q20 YoY | 3Q20 QoQ | 2020 Guide |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | **381.7** | **88%** | **83%** | **104.5** | **84.8** | **103.7** | **88.7** | **67.3** | **107.0** | **123.9** | **-36%** | **26%** | **19%** | **16%** | **420** |
| Central lab | 276.3 | 83% | 71% | 72.8 | 63.4 | 69.3 | 70.8 | 46.1 | 74.6 | 89.9 | -37% | 18% | 30% | 21% | |
| In-hospital | 87.7 | 209% | 164% | 26.6 | 16.3 | 30.7 | 14.1 | 17.1 | 27.6 | 31.7 | -36% | 69% | 3% | 15% | |
| Pharma | 17.7 | 15% | 25% | 5.1 | 5.1 | 3.7 | 3.8 | 4.1 | 4.8 | 2.3 | -20% | -6% | -39% | -52% | |
| | | | | | | | | | | | | | | | |
| **Gross profit** | **273.3** | **88%** | **102%** | **78.1** | **62.1** | **78.2** | **55.0** | **44.8** | **78.4** | **91.6** | **-43%** | **26%** | **17%** | **17%** | |
| | | | | | | | | | | | | | | | |
| **Total opex** | **442.4** | **54%** | **49%** | **89.7** | **90.5** | **111.8** | **150.5** | **104.1** | **151.4** | **216.2** | **16%** | **67%** | **93%** | **43%** | |
| R&D (excl. SBC) | 147.5 | 114% | 43% | 30.7 | 34.3 | 36.8 | 45.7 | 37.9 | 45.9 | 58.7 | 24% | 34% | 60% | 28% | |
| S&M (excl. SBC) | 152.0 | 52% | 49% | 26.3 | 34.4 | 42.1 | 49.3 | 29.6 | 37.5 | 43.9 | 12% | 9% | 4% | 17% | |
| G&A (excl. SBC) | 120.8 | 18% | 40% | 31.2 | 20.0 | 29.8 | 39.8 | 32.6 | 40.6 | 44.9 | 5% | 102% | 50% | 10% | |
| SBC | 22.1 | | | 1.5 | 1.8 | 3.1 | 15.7 | 4.0 | 27.4 | 68.7 | | | | | |
| Operating profit | (169.1) | | | (11.6) | (28.5) | (33.6) | (95.5) | (59.3) | (73.0) | (124.6) | | | | | |
| | | | | | | | | | | | | | | | |
| **GP margin** | **71.6%** | | | **74.8%** | **73.2%** | **75.4%** | **62.0%** | **66.5%** | **73.3%** | **73.9%** | | | | | |
| Total opex / revenue | 116% | | | 86% | 107% | 108% | 170% | 155% | 142% | 175% | | | | | |
| S&M expenses | 40% | | | 26% | 41% | 41% | 55% | 44% | 36% | 36% | | | | | |

Note:
SBC – share based compensation

# Appendix
## 6-cancer test sensitivity by cancer type and stage

### Sensitivity and Specificity - Correct#/Total# (%)

| Cancer | Group | I | II | III | IV | Overall |
|---|---|---|---|---|---|---|
| Lung | Train | 10/20 (50.0) | 10/14 (71.4) | 4/7 (57.1) | 8/9 (88.9) | 32/50 (64.0) |
| | Test | 6/16 (37.5) | 12/16 (75.0) | 9/14 (64.3) | 14/15 (93.3) | 41/61 (67.2) |
| Colorectal | Train | 7/9 (77.8) | 12/12 (100.0) | 14/15 (93.3) | 10/10 (100.0) | 43/46 (93.5) |
| | Test | 10/15 (66.7) | 10/13 (76.9) | 14/14 (100.0) | 15/15 (100.0) | 49/57 (86.0) |
| Liver | Train | 16/20 (80.0) | 7/8 (87.5) | 14/14 (100.0) | 6/6 (100.0) | 43/48 (89.6) |
| | Test | 13/15 (86.7) | 13/14 (92.9) | 14/15 (93.3) | 13/13 (100.0) | 53/57 (93.0) |
| Ovarian | Train | 1/5 (20.0) | 2/5 (40.0) | 33/37 (89.2) | 3/3 (100.0) | 39/50 (78.0) |
| | Test | 2/6 (33.3) | 5/11 (45.5) | 20/22 (90.9) | 13/14 (92.9) | 40/53 (75.5) |
| Pancreatic | Train | 7/11 (63.6) | 7/11 (63.6) | 8/9 (88.9) | 8/9 (88.9) | 30/40 (75.0) |
| | Test | 15/18 (83.3) | 12/14 (85.7) | 10/13 (76.9) | 12/14 (85.7) | 49/59 (83.1) |
| Esophageal | Train | 4/8 (50.0) | 11/13 (84.6) | 13/15 (86.7) | 4/4 (100.0) | 32/40 (80.0) |
| | Test | 7/13 (53.8) | 15/19 (78.9) | 13/16 (81.3) | 16/16 (100.0) | 51/64 (79.7) |

| | Group | I | II | III | IV | Overall |
|---|---|---|---|---|---|---|
| Sensitivity | Train | | | | | 219/274 (79.9) |
| | Test | | | | | 283/351 (80.6) |
| Specificity | Train | | | | | 194/195 (99.5) |
| | Test | | | | | 283/288 (98.3) |