Glycotest

A New Paradigm for Early Diagnosis and Surveillance For Liver Cancer

Lawrence Cohen, CEO
77 Water Street , Suite 817
New York, NY 10005
Lawrence.Cohen@Glycotest.com
+1 646-354-8361
www.glycotest.com

Disclaimer

This presentation is being furnished on a confidential basis to "accredited investors." By its acceptance hereof, each recipient agrees that this presentation may not be reproduced or distributed to others, at any time, without the prior written consent of Glycotest, Inc. ("Glycotest" or "we" or the "Company") and that the recipient will keep permanently confidential all information contained herein not already in the public domain. This presentation is not an offer to sell or the solicitation of an offer to purchase securities. Any such offer or solicitation will be made only by means of definitive documents governing the issuance of any such securities. In the event of any conflict between the information contained in this document and the definitive documents governing issuance of securities, such definitive documents shall control.

This presentation includes forward-looking statements that involve risk and uncertainty. Sentences or phrases that use words such as "expects", "believes", "anticipates", "hopes", "plans", "may", "can", "will", "projects", and others, are often used to indicate forward-looking statements, but their absence does not mean a statement is not forward-looking. Such statements reflect Glycotest's current opinion and are designed to help readers understand Glycotest's thinking. By their very nature, however, such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

A New Paradigm for Early Diagnosis and Surveillance For Liver Cancer

- **Commercial clinical laboratory services for patients at risk for liver cancer with issued patents to >50 glycoprotein biomarkers**
- **$1B opportunity—huge and growing populations with viral and non-viral hepatitis driving progressive fibrosis, liver cancer risk and need for effective disease surveillance**
- **Current blood tests and imaging modalities have low sensitivity and/or specificity—curable early-stage disease is being missed**
- **Glycotest's lead product—HCC Panel—significantly outperforms currently dominant blood test (AFP) in independent 208, 127 and 149 patient head-to-head clinical studies**
- **Seeking $10MM Series A financing to advance towards commercialization of the HCC Panel**
  - *Launching in H2 2019*
  - *Profitable in Q1 2021—expected 2022 revenue $116MM*

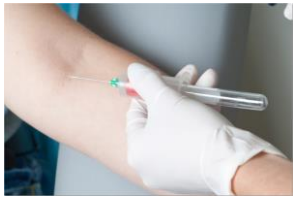
Overview

- **Glycotest, Inc.**
  - *Founded 2012 on technology innovated at the Baruch S. Blumberg Institute and Drexel University College of Medicine (Philadelphia)*
  - *Glycotest technology has benefitted from $8.9MM in grants to the innovators over past years*
  - *Proprietary blood-based biomarkers, panels and algorithms*
  - *Five US and eight ex-US patents issued or allowed; additional patents pending*

- **Focused on liver cancer surveillance**
  - *Large at-risk population— >100 MM US and >2 B global*
  - *3.1 MM patients in the US are currently candidates for liver cancer surveillance*
  - *Lead product—biomarker panel for hepatocellular carcinoma (HCC Panel) to score likelihood of disease*

Glycotest Process for Surveillance and Early Diagnosis of Liver Cancer

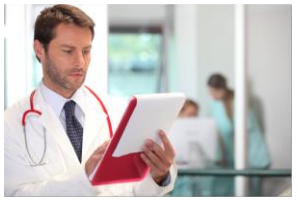
Physician orders HCC Panel.



Serum sample taken for delivery to Glycotest.

Glycotest receives serum sample for analysis in Glycotest's CLIA laboratory.

Analysis leads to HCC Panel disease likelihood score sent to physician.

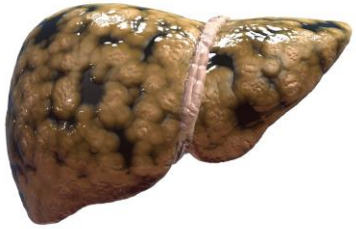


HCC Panel score considered in patient's care.

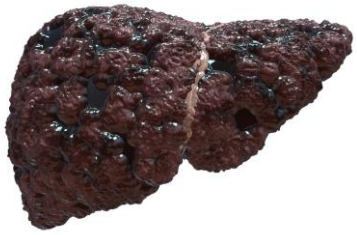
HCC Panel score informs clinical decisions like confirmatory diagnosis by CT or MRI.

$1B Opportunity

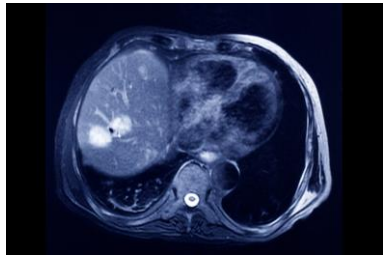
- **Huge and growing populations with viral and non-viral hepatitis—driving progressive fibrosis, liver cancer risk and need for effective disease surveillance**
  - *Chronic hepatitis B: 2.2 MM US; 360 MM WW; incurable*
  - *Chronic hepatitis C: 3.2 MM US; 170 MM WW; liver cancer risk persists despite cure*
  - *Fatty liver disease and NASH / ASH: >100 MM US; >1.5 B WW; rapidly growing populations due to obesity and metabolic disease*
  - *Cirrhosis: 3.2 MM US; 73 MM WW; secondary to hepatitis; proximate cause of most liver cancer*



Fatty Liver



Cirrhosis



Hepatocellular Carcinoma

Current Disease Surveillance Tests Don't Work

- **Current blood tests and imaging modalities have low sensitivity and/or specificity**
  - *AFP—best current blood test for hepatocellular carcinoma (HCC; major form of liver cancer) but USA clinical guidelines recommend optional use only in combination with ultrasound—misses >50% of disease (AFP-negative disease)*
  - *Ultrasound—only HCC surveillance test definitively recommended by USA clinical guidelines—highly operator dependent; low sensitivity*
- **Curable early-stage disease is being missed**
  - *HCC is the fastest growing cause of cancer mortality in the US—will surpass breast cancer within 8 years*
- **Effective disease surveillance tests are critical unmet clinical needs**
  - *Liver cancer tests to identify curable early-stage disease*
  - *Liver fibrosis test to stage disease and determine when to treat hepatitis*

KOL Perspectives

- **Critical unmet clinical need for an effective HCC surveillance test**
- **Chronic HBV, HCV and huge NAFLD / NASH population are key at-risk groups**
- **HCC risk persists after chronic HCV cure by antiviral therapy or transplant**
- **Recognition of HCC risk from NAFLD / NASH increasing**
- **Early-stage and AFP-negative disease detection are key**
- **Long-term disease-free survival possible for treatable early-stage HCC**

Nathan Bass, MD, PhD. Gastroenterology. Professor; Site Director, NASH Clinical Research Network; University of California, San Francisco Medical Center.

Douglass Dietrich, MD. Gastroenterology. Professor, Division of Liver Diseases; Icahn School of Medicine at Mount Sinai.

Scott Friedman, MD. Gastroenterology. Dean for Therapeutic Discovery; Fishberg Professor of Medicine; Professor of Pharmacology and Systems Therapeutics; Chief, Division of Liver Diseases; Icahn School of Medicine at Mount Sinai.

John Lake, MD. Hepatology/Gastroenterology. Director, Division of Gastroenterology, Hepatology and Nutrition; Director, Liver Transplant Program; University of Minnesota Medical Center.

Alan Venook, MD. Oncology (liver and colorectal cancers). Madden Family Distinguished Professorship in Medical Oncology and Translational Research; University of California, San Francisco Medical Center.

Value Proposition

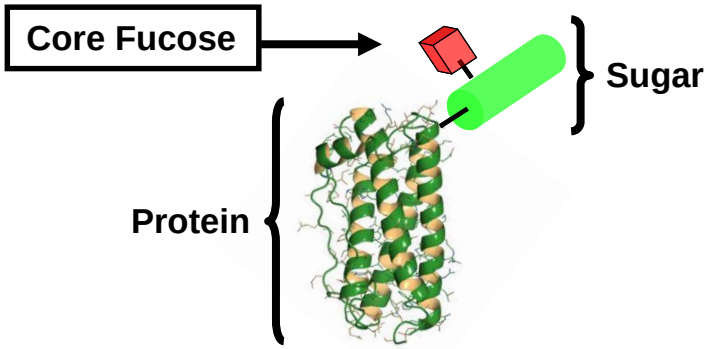
- **Glycotest is at the forefront in surveillance for early stage liver cancer**
  - *Well defined critical unmet clinical needs*
  - *Large and growing US and global markets*
  - *No currently available technology solutions*
  - *Glycotest has the proprietary biomarkers, assay technology and algorithm to provide physicians with actionable information*

- **Liver cancer surveillance drives lower healthcare costs**
  - *Early detection of HCC enables lower cost curative therapy—resection or ablation*
  - *Later stage HCC is only eligible for higher cost palliative therapy—TACE or chemotherapy*
  - *Cost effective HCC panel will enable early-stage HCC detection, lower cost treatment options, and better patient outcomes that will drive market adoption*

- **Estimated market value for the HCC Panel is $818 MM in the US alone**
  - *Assumes only 620,000 US patients under surveillance—20% of 3.1 MM eligible patients*

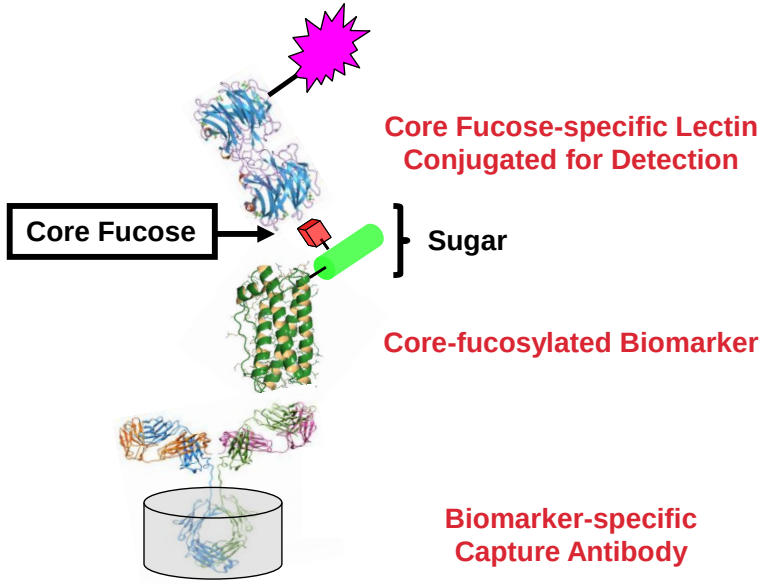
Proprietary Serum Biomarkers and Assay Technology

- **Proprietary serum biomarkers with unique core fucose chemistry**
  - *Issued patents to >50 glycoprotein biomarkers—*
    liver-secreted acute phase proteins associated with inflammation and stress
  - *Unique abnormal change in sugar structure in liver disease—*
    core fucose disease signal



A Glycotest Glycoprotein Biomarker

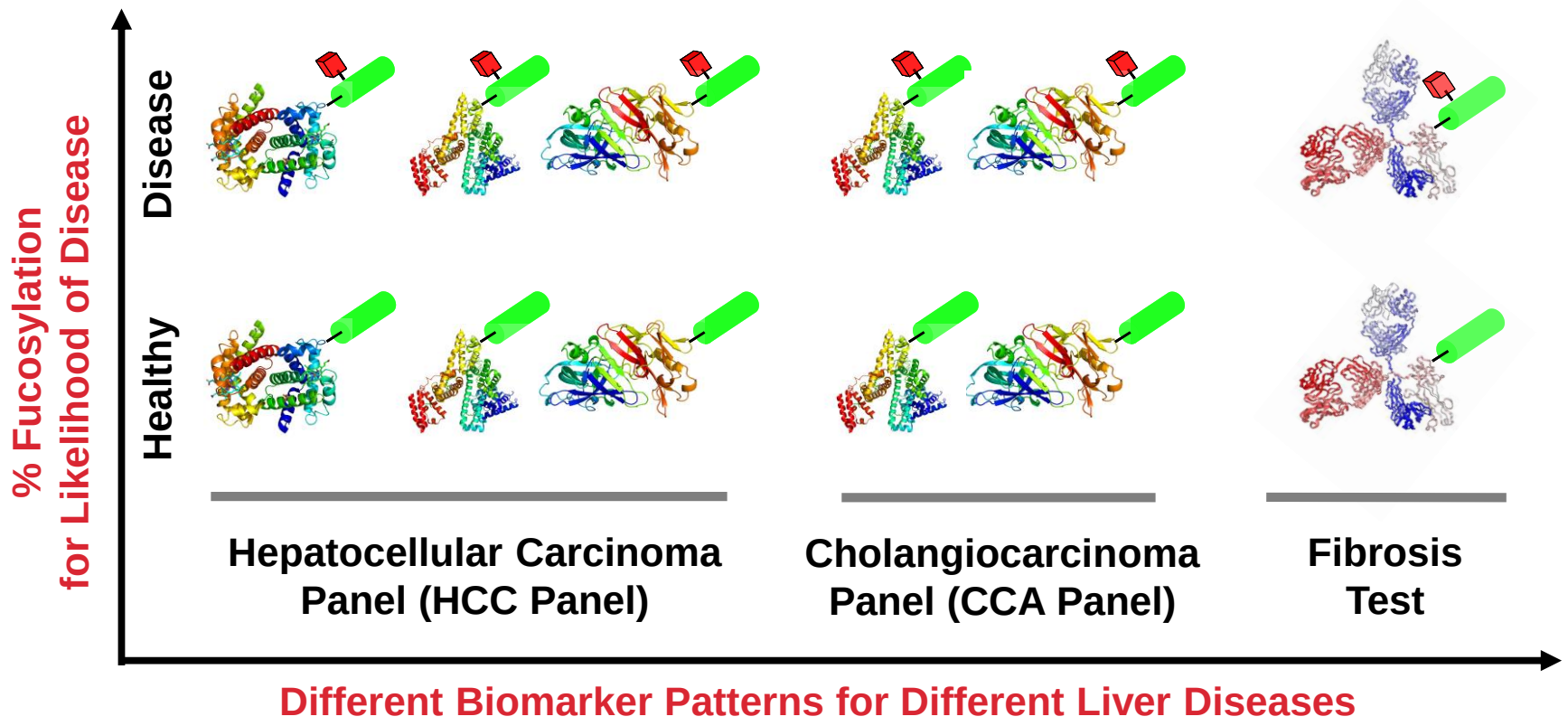
- **Proprietary assay technology optimized for core fucose quantification**
  - *Based on convenient immunoassay methodology*
  - *Exploits recombinant lectins engineered for core fucose specificity*



Glycotest Core Fucose-specific Assay Technology

Proprietary Biomarker Panels, Algorithms and Single Biomarker Tests

- **New tests to address serious unmet clinical needs**
  - *Refer asymptomatic patients with worsening liver disease for additional care*
  - *Detect curable early-stage disease*



Intellectual Property—13 Patents Issued or Allowed

- **HCC Panel patent application (PCT/US2017/018040 and Taiwan 106106107)**
  - *One of two most important Glycotest patent families—protects Glycotest HCC Panel test*
  - *Fresh application providing protection to 2037, including in China*
- **PCT/US2010/044307**
  - *Second of two most important Glycotest patent families—protects engineered lectins for fucosylated biomarker assays*
  - *Issued European (2462240) and Chinese (ZL201080044720.8) patents*
  - *Protection to 2030, including in China*
- **PCT/US2006/017478**
  - *Methods for diagnosing liver disease using fucosylated biomarkers*
  - *Issued US (7,776,550; 8,183,000), Australian (2006244398; 2012247075; 2015275300), Japanese (5964769; 6184935) patents and allowed US and Canadian patents*
  - *Protection to 2026*
- **US2009/0253180**
  - *Methods for diagnosing liver disease using fucosylated LRAGG*
  - *Issued (9,110,078) and allowed US patents*
  - *Protection to 2028*
- **Trade Secrets**
  - *Fucosylated biomarker assay manufacturing technology*
  - *Fucosylated biomarker assay methods*

Lead Product—HCC Panel

- **Algorithm-driven panel—surveillance for curable HCC**
  - *To detect curable early-stage disease*
  - *To provide a convenient blood test that guides CT / MRI confirmation*
  - *For patients at risk due to both viral and non-viral hepatitis*
- **Early-stage HCC is curable**
  - *Resection and ablation lead to long-term disease free survival*
  - *Curative treatment is less costly than palliative care for later stage disease*
- **Large and expanding population needs an effective HCC surveillance solution**
  - *Cirrhosis + chronic hepatitis B w/o cirrhosis—3.1 MM US; 323 MM WW*
  - *NASH pandemic expanding market*
  - *Chronic testing opportunity—repeat testing every 3-6 months*
- **Glycotest's HCC Panel significantly outperforms currently dominant blood test (AFP) in independent 208 patient, 127 patient and 149 patient head-to-head clinical studies**

Clinical Feasibility Studies—Head-to-head Comparison of the Glycotest HCC Panel to AFP

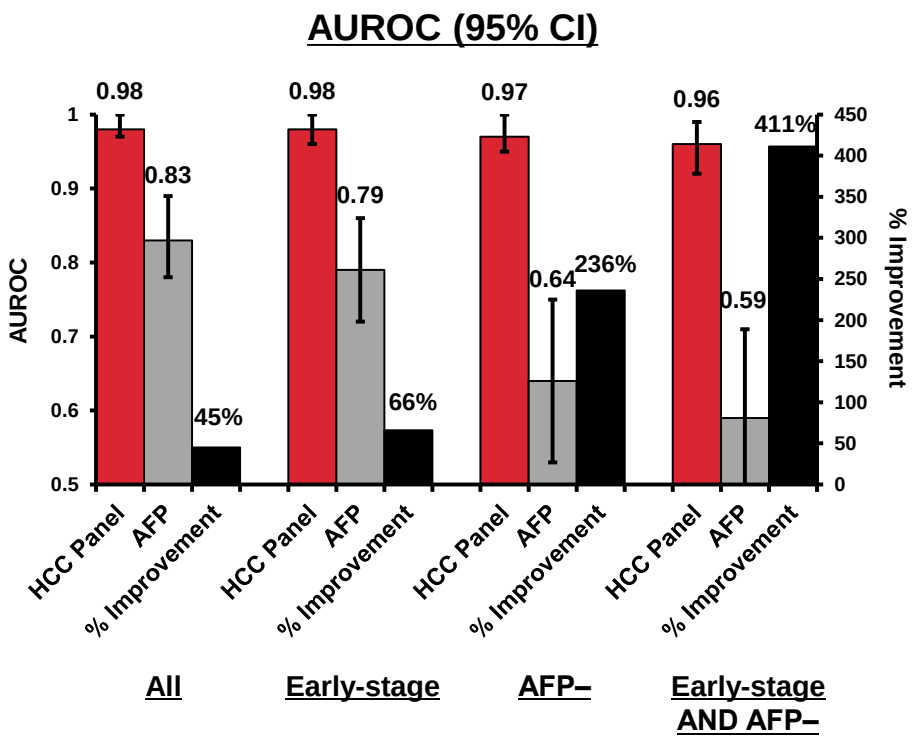
- **Three independent clinical feasibility studies (case–control studies)**
- **Collaborations between Glycotest innovator (Anand Mehta; patient sample assays and data analysis) and clinical collaborators (patient samples)**
- **Patient samples collected under IRB-approved protocols**
- **Patient cohorts assembled by clinical collaborators**
- **Glycotest innovator blinded to clinical data until after samples were assayed**
- **Study 1 stratified by curable early stage HCC (T1 + T2) and AFP-negative disease (< 20 ng/mL)**
- **Study 2 stratified by HCC disease stage (curable HCC: T1; T2; T1 + T2)**
- **Study 3 stratified by curable early stage HCC (T1 + T2) and AFP-negative disease (< 20 ng/mL)**
- **Chronic hepatitis B patients (76% of Study 2 control patients) predominantly Asian**
  - *No evidence of Western–Asian difference in these studies or published clinical data on individual biomarkers*
- **Additional information available in supplementary document**

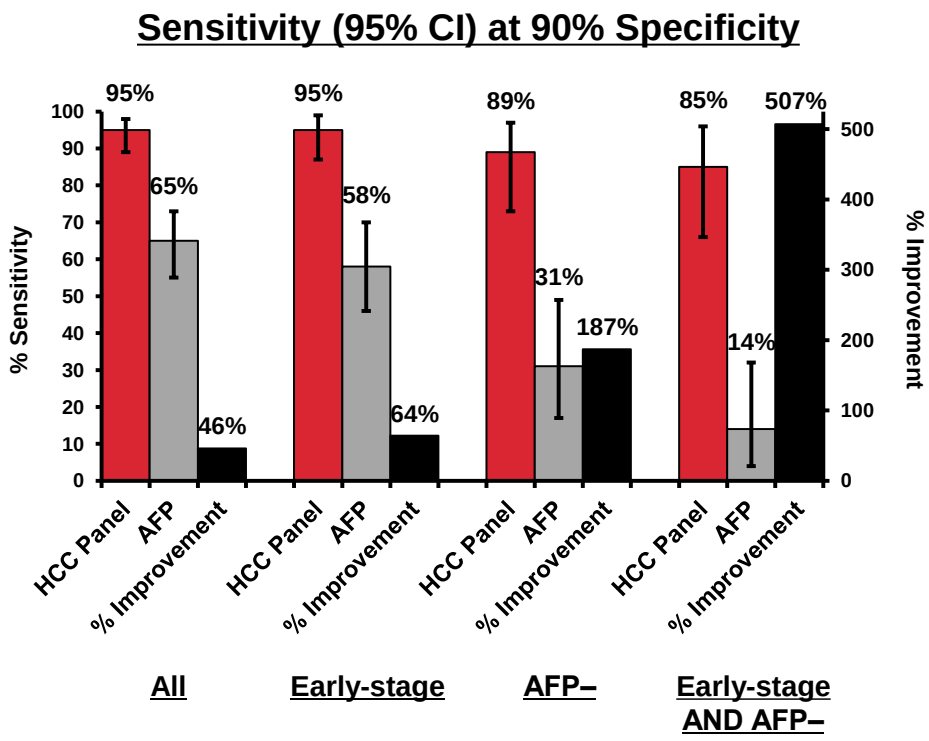
T1: 1 lesion < 2 cm
T2: 1 lesion 2–5 cm or ≤ 3 lesions < 3 cm

HCC Panel—First Clinical Study

Glycotest

Performance Superior to AFP for the Discrimination Of Early-stage and AFP-negative HCC from Cirrhosis



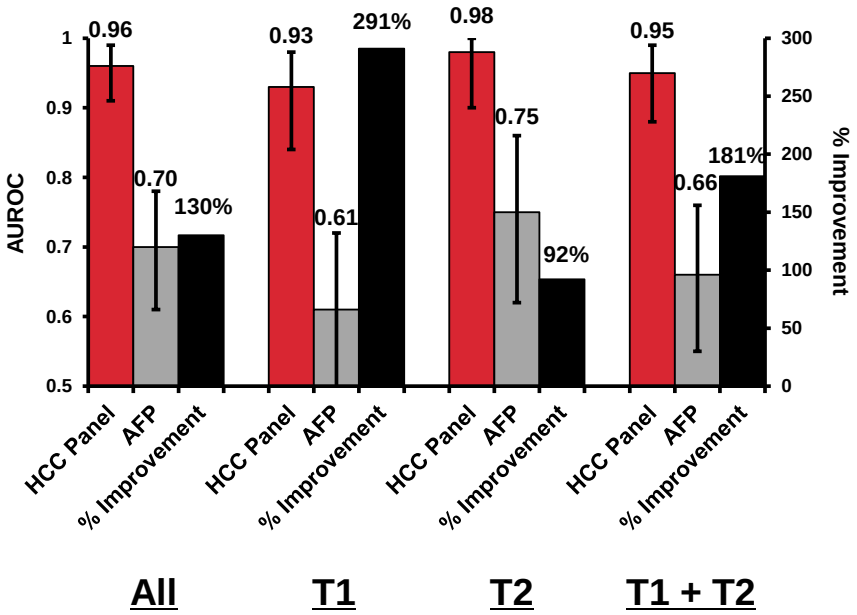


All: HCC (N=115) vs. cirrhosis (N=93)
Early-stage: HCC UNOS stage T1/T2 (N=69) vs. cirrhosis (N=93)
AFP⁻ (< 20 ng/mL): HCC (N=39) vs. cirrhosis (N=84)
Early-stage AND AFP⁻: HCC (N=29) vs. cirrhosis (N=84)
HCC Etiology (%): HCV (61); HBV (6); Other (33)
Cirrhosis Etiology (%): HCV (48); HBV (10); Other (42)

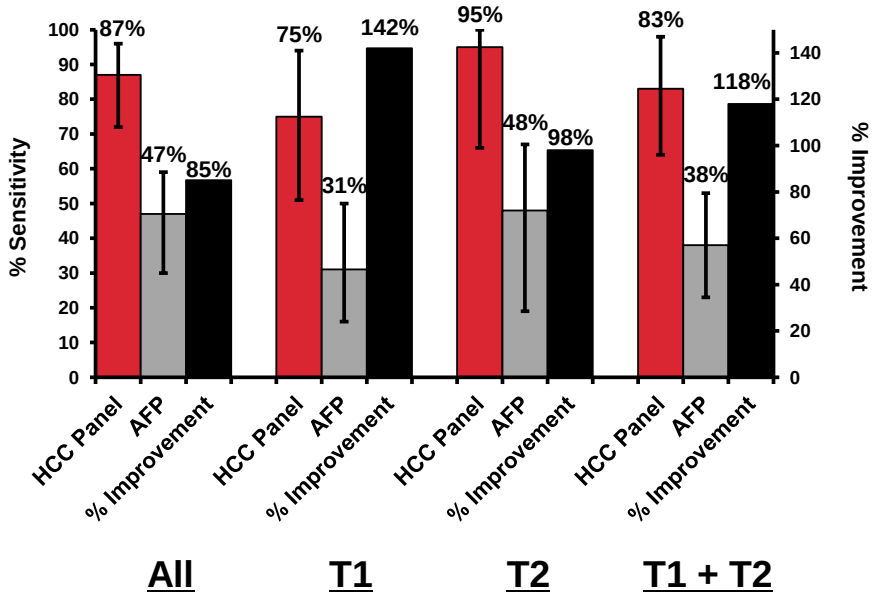
HCC Panel—Second Clinical Study

Independent Confirmation of Performance Superior to AFP for Detecting Early-stage HCC

AUROC (95% CI)



Sensitivity (95% CI) at 90% Specificity



All: HCC (N=93) vs. chronic liver disease (N=34)
HCC stage: T1 N=32; T2 N=21; T3-4 N=20; unknown stage N=20
Chronic liver disease: cirrhosis N=9; HBV N=22; HCV N=2; ALD N=1

HCC Panel—Third Clinical Study

Performance Superior to AFP for the Discrimination Of Early-stage and AFP-negative HCC from non-HCC Controls

- **Entire Cohort**
  - *HCC cases N = 75; non-HCC controls N = 74*
  - *HCC Panel AUROC = 0.97 (95% CI 0.94 – 1.00); 93% sensitivity @ 92% specificity*
  - *AFP AUROC = 0.88 (95% CI 0.83 – 0.94); 71% sensitivity @ 92% specificity*
- **Early-stage Cohort (T1 + T2)**
  - *HCC cases N = 24; non-HCC controls N = 74*
  - *HCC Panel AUROC = 0.96 (95% CI 0.91 – 1.00); 88% sensitivity @ 91% specificity*
  - *AFP Panel AUROC = 0.87 (95% CI 0.77 – 0.97); 75% sensitivity @ 91% specificity*
  - *The HCC Panel identified 78% of the HCC patients missed by AFP*
- **AFP-negative Cohort (AFP < 20 ng/mL)**
  - *HCC cases N = 29; non-HCC controls N = 72*
  - *HCC Panel AUROC = 0.93 (95% CI 0.85 – 1.00); 86% sensitivity @ 90% specificity*
  - *AFP AUROC = 0.73 (95% CI 0.62 – 0.83); 34% sensitivity @ 90% specificity*
  - *The HCC Panel identified 86% of the HCC patients missed by AFP*

KOLs Regard HCC Panel Clinical Data to be Highly Promising

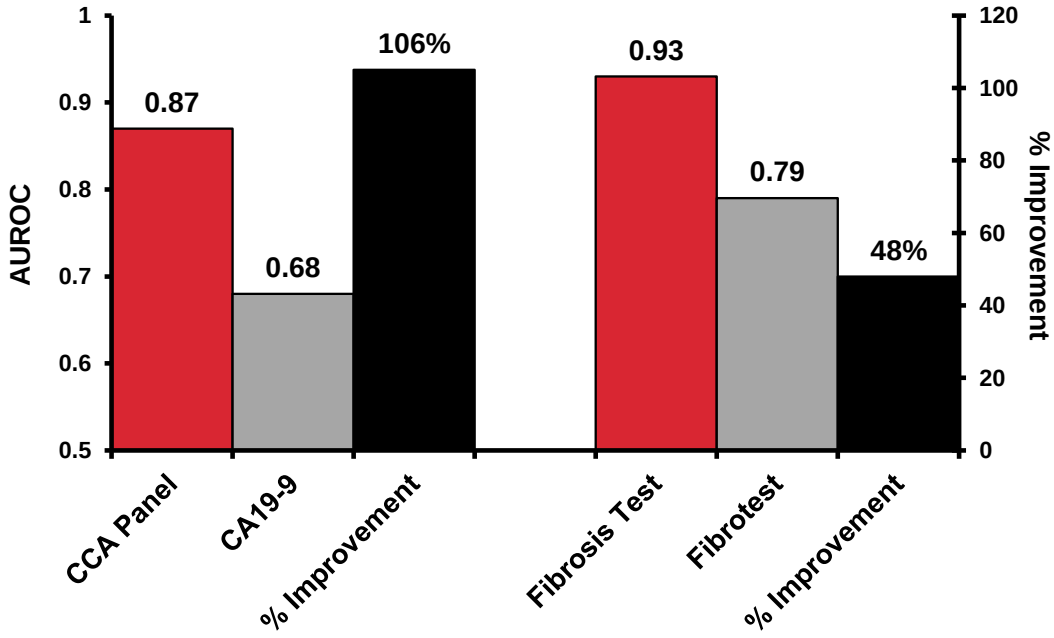
- **Glycotest engaged a market research firm (Defined Health) to determine how experts assessed Glycotest's HCC Panel**
- **Defined Health conducted telephone interviews with 5 US hepatologists**

Title	Affiliation
• Professor of Medicine • Medical Director of Liver Tumor Program • Director of Hepatology • Chief of Hepatology • Professor of Medicine	• Harvard Medical School • East Carolina University • UT Southwestern Medical Center • Stanford University • UT Southwestern Medical Center

- **Comments from the experts interviewed:**
  - *"If you can have 95% sensitivity at a 90% specificity, that's wonderful."*
  - *"Surely as I look at these AUROCs they look mighty good. It's pretty hard to do better than 97-98% AUROCs. It's pretty good numbers here."*
  - *"With these numbers, this test could replace the need for US."*
  - *"This is better [than US+AFP]. No question about it."*
  - *"Specifically the ability to detect early and AFP negative tumors, I think is attractive."*

Pipeline—CCA Panel; Fibrosis Test

- **CCA Panel for cholangiocarcinoma surveillance**
- **Fibrosis Test for staging intermediate fibrosis**



AUROCs >0.9 and/or >20% higher (0.5–1 AUROC range) than comparators are clinically meaningful improvements.

CCA (cholangiocarcinoma) Panel: CCA (N=39) vs. primary sclerosing cholangitis (N=31)

Fibrosis Test: discrimination of intermediate stage fibrosis; Ishak Stage F1-2 (N=24) vs. F3-6 (N=178; Glycotest; Mehta, AS, et al. J Virol. 2008; 82:1259-1270.); Ishak Stage F0-2 vs. F3-6 (HCV FibroSURE; historical data: Halfon, P, et al., Am J Gastroenterol. 2006; 101:547-555.)

Go-to-Market Plan—HCC Panel

- **Business model**
  - *US: Commercialize Laboratory Developed Test (LDT) service products in CLIA lab—regulated by CMS, not FDA*
  - *Ex-US strategy: Partner for large Asian liver disease markets*
- **Commercial launch strategy**
  - *Commercial assay manufacturing development with CROs*
  - *Enable HCC Panel in CLIA lab—complete analytical validation, pre-analytical effects, algorithm training*
  - *Complete prospective clinical validation study for commercial launch*
  - *KOL engagement and aggressive publication program to support marketing*
- **Coverage and reimbursement strategy**
  - *Developed with QURE Healthcare and Morgan Lewis*
  - *Conduct planned clinical utility studies with QURE*
  - *Register the HCC panel and seek Medicare coverage through Palmetto MolDX program*
  - *Positive decision from Palmetto will influence private payer policies*
  - *High margin HCC Panel test projected by preliminary value-based pricing study*

Liver Cancer Test Competition

Glycotest

Feature	AFP	Wako Blood Tests		Imaging			Glycotest HCC Panel + Algorithm
		AFP-L3	DCP	Ultrasound	CT	MRI	
Effective for Early-stage HCC	No	No	No	No	No	No	Yes
Effective for AFP-negative HCC	No	No	No	Yes	Yes	Yes	Yes
Operator Independent	Yes	Yes	Yes	No	Yes	No	Yes
No Difficulty in Obese Patients	Yes	Yes	Yes	No	Yes	No	Yes
In USA Clinical Guidelines for Surveillance	Optional	No	No	Yes (marginal sensitivity)	No	No	Not Yet!

Team, Advisors and Key Resources

Management

Lawrence Cohen, CEO
Charles Swindell, PhD, COO
George Hu, Director, Asian BD

Innovator–Advisors
Timothy Block, PhD; Blumberg Institute, Hepatitis B Foundation
Anand Mehta, DPhil; Medical University of South Carolina

Senior Clinical Advisor; MAB Chair
David Chernoff, MD; Industry Veteran
(Crescendo; XDx; CardioDx; Tethys; Chiron; Elan)

Clinical Study Support and Management
DOCRO (oncology diagnostics CRO)

Manufacturing
Precision Antibody (reagent specialist)
Radix BioSolutions (assay specialist)

Regulatory Affairs and Compliance
Elizabeth Lison; Advocea (IVD specialist)

Quality
Michael Kochersperger; Veteran Quality Consultant

Corporate Counsel
Fahd Riaz; DLA Piper

Coverage and Reimbursement
QURE Healthcare (health economics firm)
Andrew Ruskin; Morgan Lewis

Intellectual Property Counsel
Baker & Hostetler

Finance, HR and IT
NetScientific

Initial Medical Advisory Board

- **David Chernoff, MD, Chair**
  - *Molecular Dx industry veteran*
  - *Crescendo; XDx; CardioDx; Tethys; Chiron; Elan*
- **Scott Friedman, MD**
  - *Icahn School of Medicine at Mount Sinai, New York*
  - *Dean for Therapeutic Discovery; Chief, Division of Liver Diseases; Fishberg Professor of Medicine; Professor of Pharmacology and Systems Therapeutics*
  - *Gastroenterology*
- **Douglas Dieterich, MD**
  - *Icahn School of Medicine at Mount Sinai, New York*
  - *Director, Institute for Liver Medicine, Mount Sinai Health System; Professor of Medicine*
  - *Gastroenterology*

Current Status and Timeline

- **Progress to date**
  - *Individual biomarker evaluation in >800 patients*
  - *Basic HCC algorithm development in 1000s of patients*
  - *Three HCC Panel vs. AFP clinical studies in >480 patients*
  - *HCC Panel clinical validation study plan developed; investigators and sites identified*
  - *HCC Panel coverage and reimbursement strategy developed; clinical utility and value-based pricing plans developed*
  - *Pipeline opportunities in cholangiocarcinoma and fibrosis–cirrhosis identified*
  - *HCC panel commercial biomarker assay manufacturing methods developed*

- **Timeline to commercial launch of HCC Panel in 2019**
  - *Q2 2018: Series A funding closed*
  - *Q2 2018: Start manufacturing and clinical sample collection*
  - *Q3 2018: Initiate analytical validation*
  - *Q4 2018: Complete analytical validation, expand team*
  - *Q1 2019: Complete algorithm training*
  - *Q2 2019: Start clinical utility studies*
  - *Q2 2019: Initiate internal selling and marketing capability*
  - *Q3 2019: Complete clinical validation study; commercial launch*

Use of Funds

- **Seeking $10 MM in Series A financing to advance towards commercialization of the HCC Panel**

- **Use of funds through commercial launch (Q3 2019)**
  - *Expand team and initiate laboratory validation work*
  - *Biomarker assay manufacturing*
  - *Clinical sample collection*
  - *Analytical validation*
  - *Pre-analytical effects*
  - *Algorithm training*
  - *Clinical validation*
  - *Commercial launch*