



# Corporate Overview

September 2021

Nasdaq: BIOC  
[www.biocept.com](http://www.biocept.com)

# Forward-Looking Statements

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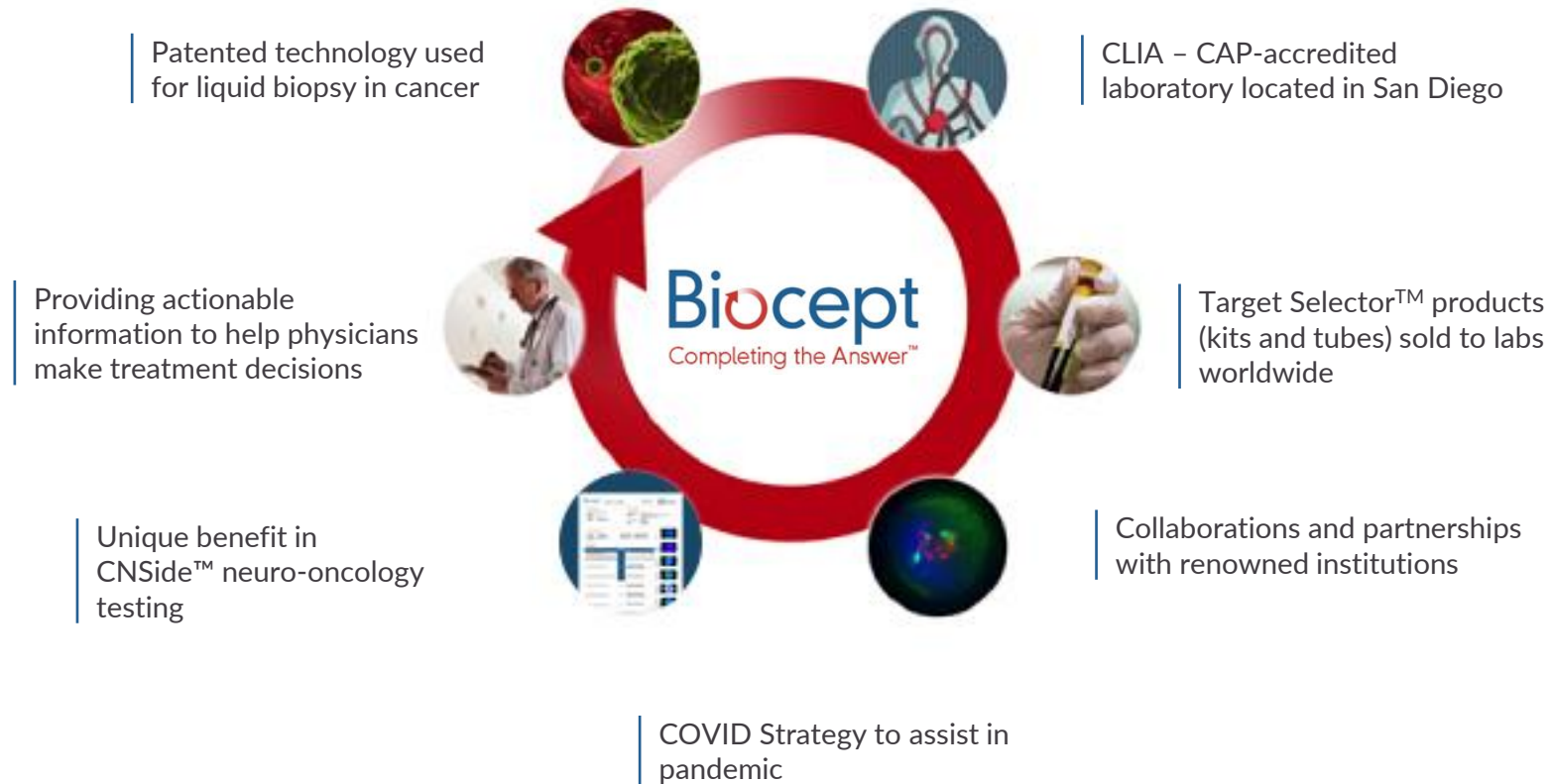
This presentation contains, and any accompanying oral presentation would no doubt contain, forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, regarding Biocept, Inc. and our business. Forward-looking statements include all statements that are not historical facts and generally can be identified by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would, or the negative of those terms and similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. For details about these risks, please see our SEC filings.

All forward-looking statements contained in this presentation speak only as of the date hereof, and except as required by law, we assume no obligation to update these forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

# Corporate Profile

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# Corporate Highlights

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## Biocept is focused on *high unmet clinical needs*

- Patients with metastatic cancer involving the central nervous system (CNS) with CNSide assay
- High-volume, high-service COVID-19 testing for skilled care facilities and institutions
- Innovative, high-value breast cancer service has gained reimbursement of >\$2,000 per assay from Medicare

## Biocept is positioned in a *\$17 billion dollar market*<sup>1</sup>

- Liquid biopsy for diagnosis, therapy decisions and monitoring in cancer for use by healthcare providers
- Focus on neuro-oncology and related areas estimated to be a \$1B market
- Collaborations in place with leading academic institutions
- Quest Diagnostics collaboration for Target Selector™ NGS lung cancer panel
- Strong balance sheet and growing revenue

## Biocept has *unique technology* to inform clinical decisions

- Patented dual tumor cell and cell-free DNA testing platforms
- CLIA, CAP validated laboratory developed tests for testing both cerebrospinal fluid (CSF) and blood
- Submit a *De Novo* Classification Request for CNSide to support a Class II IVD
- Detected biomarkers are listed in NCCN guidelines

<sup>1</sup>Liquid Biopsy Market Research Report Global Forecast to 2022,  
Market Research Future

# Biocept COVID-19 Testing

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## **~500,000 COVID-19 samples received for SARS-CoV-2 Testing since launch in June 2020**

- Average reimbursement of ~\$100 per sample
- Diverse base of business in clinics, skilled nursing and colleges leads to repeat testing per client
- Fast turnaround times with vast majority of results reported in 48 hours
- Biocept COVID-19 test is performed with TaqPath™ RT-PCR EUA molecular diagnostic platform
- Testing performed in high-complexity, CLIA-certified and BSL-2 safety level lab by licensed molecular lab staff trained to perform COVID-19 testing

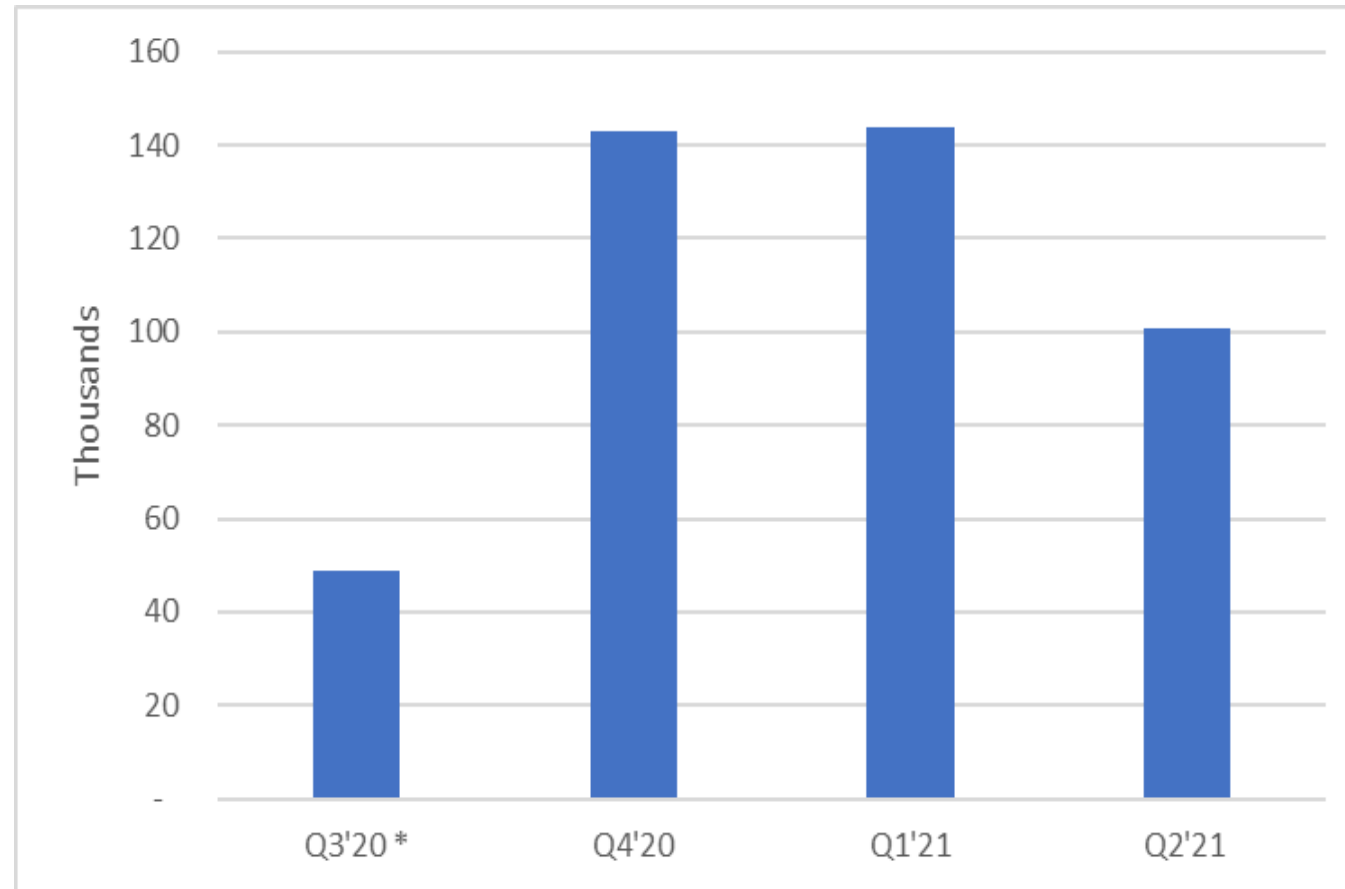
## **Supply Agreement with Aegea Biotechnologies to develop and commercialize Next Gen COVID-19 Assay**

- Agreement follows successful co-development of assay
- Quantitative results – better for monitoring
- Discerns between COVID-19 strains
- Utilize patented Switch-Blocker™ technology

# COVID-19 Volume Drives Revenue Growth

## Samples Received by Quarter

Reaching 500,000 Samples Received Milestone through August 16, 2021



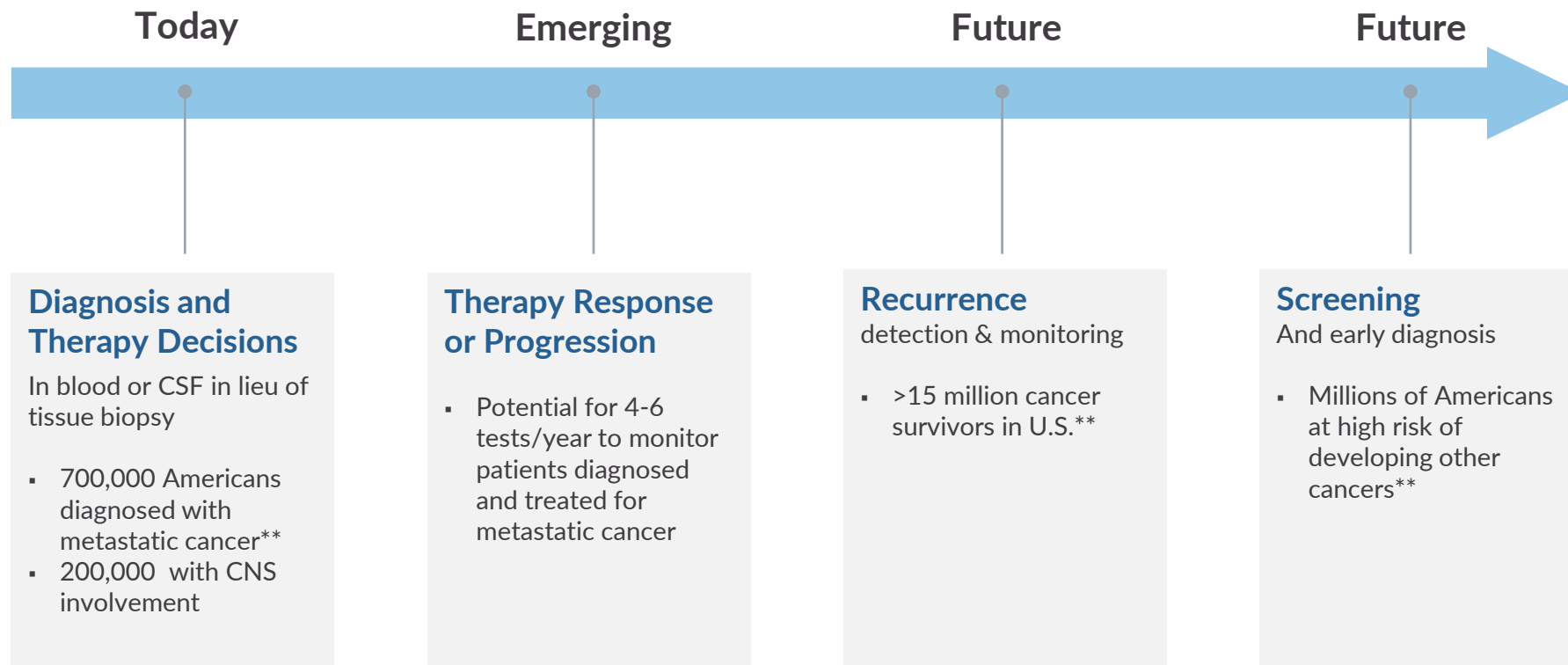
\*Includes June 2020 sample ~196

- Medicare reimbursement: \$100 per test
- COVID-19 volume drove increased capacity, automation and investment in additional molecular technologies
- Expands capabilities in core oncology business

# Core Strategy - Liquid Biopsy Market for Oncology



Estimated  
**\$17 billion**  
market by  
2023\*



**Biocept focuses on patients with advanced or metastatic cancers including those with CNS involvement**

\*International Liquid Biopsy Market Report, Market Research Future, August 18, 2018

\*\*American Cancer Society: Cancer Treatment and Survivorship 2016-2017

# Biocept Advantage

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## Biocept's Proprietary Cell Capture System

- Allows for detection and monitoring of tumor cells in blood and CSF
- Clear construction allows for protein and gene detection
- Flexible platform validated for multiple tumor types
- Chemistry plus capture device

## Biocept's High Sensitivity Molecular Testing Offerings

- Sensitivity as low as .05%
- Clinically actionable genes
- Performed via qPCR or NGS
- Available as RUO products or CE-IVD kits for use in external labs

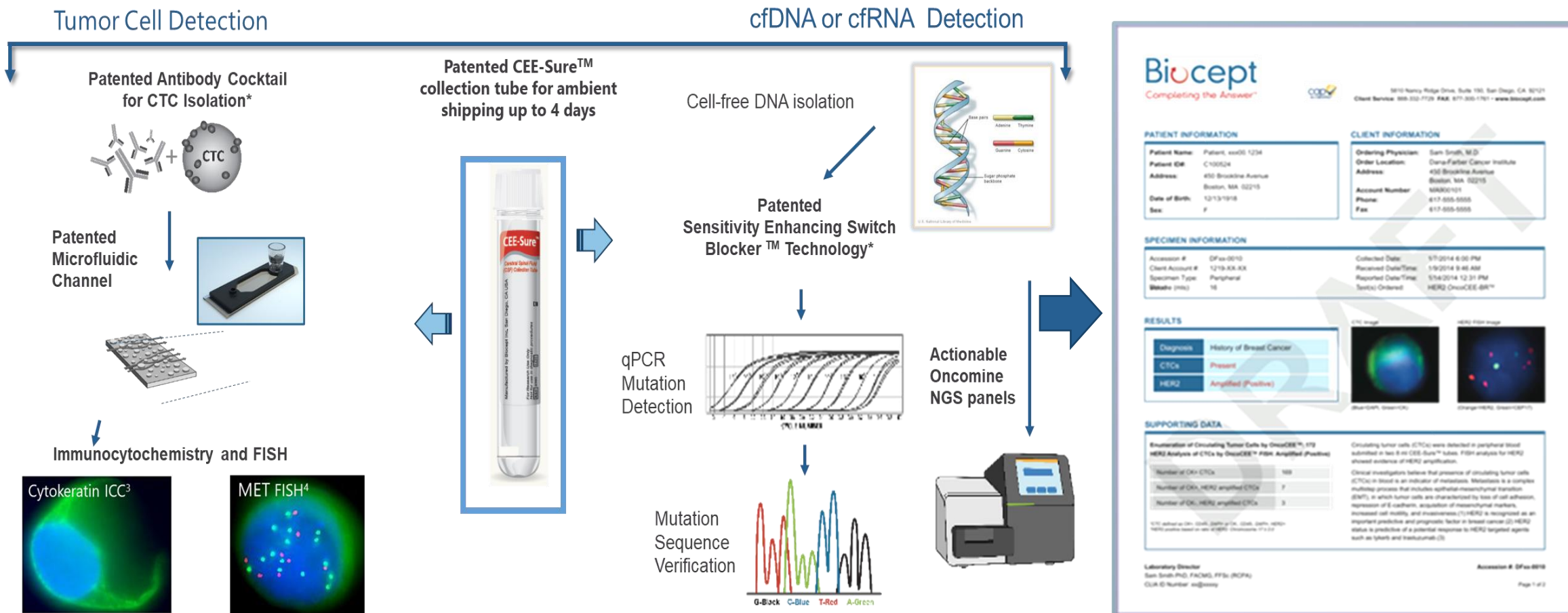
## Subspecialty Focus on Neuro-Oncology with



- Area of high unmet clinical need; limited diagnostic tests available to assess CNS involvement by cancer
- Strong KOL engagement and growing participation in both commercial cases and clinical studies
- Goal to get testing into NCCN guidelines and become standard of care
- CNSide evaluates CNS involvement and tests for clinically actionable biomarkers
- Provides results for patient management and therapy decisions for use by healthcare providers

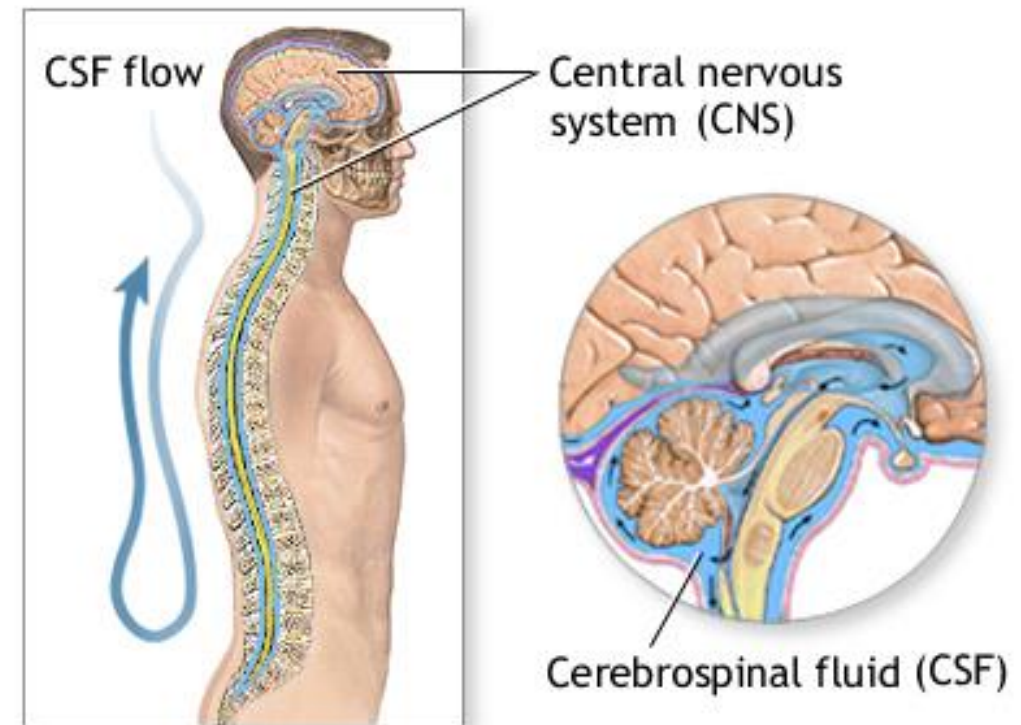
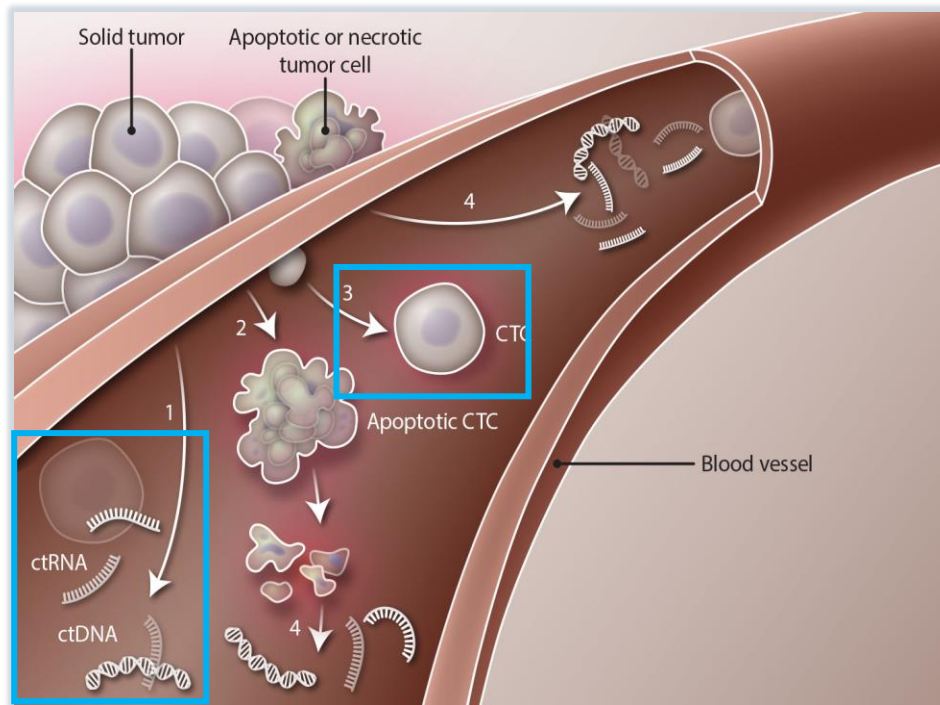


# Biocept Proprietary Technology and Workflow



# Biocept Identifies Targets - From Blood or CSF

- **CTCs** are whole cells containing intact genomic material shed from tumors including DNA, RNA and protein
- **ctDNA** and **ctRNA** are fragmented DNA or RNA shed into the **blood** and **CSF** as cells die
- *Biocept analyzes CTCs, ctDNA and ctRNA for diagnosis and biomarker status*



Credit: H. McDonald / Science Translational Medicine

# **CNSide**™ Answers Questions Required for Optimal Treatment

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## 1. **Is there tumor?**

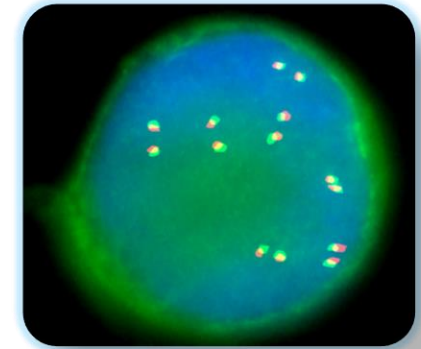
Biocept detects cancer cells in CSF with a sensitive, quantitative method vs. qualitative CSF cytology

## 2. **Is there a target to inform a treatment decision?**

If tumor is found, Target Selector™ can identify actionable genomic targets that inform clinical decision making

## 3. **Is there a trend?**

Quantitative Monitoring for CSF tumor cells can indicate response or progression



# **CNSide**<sup>TM</sup> s 1<sup>st</sup> Liquid Biopsy Intended for Diagnosis of CNS Involvement

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## Meets High Unmet Clinical Need

- 10-30% of cancer patients develop CNS involvement – over 200,000/year
- Avoids repeated lumbar punctures and surgical biopsies

## Leverages Biocept's Core Technology

- Cell capture and molecular characterization of tumor cells in CSF
- Guides therapy decisions with detection of tumor cells and biomarkers
- Quantitative cell count, qPCR and NGS used to gauge therapy response

## Potential to Improve Upon Existing Standard of Care


- Early data from feasibility studies suggest Biocept is superior to standard of care – cytology<sup>1</sup>
- Cytology can require up to 3x for LMD diagnosis in NCCN guidelines currently
- Cytology is not quantitative and is not adequate for therapy monitoring

<sup>1</sup>Berz et al, Poster, IASLC, 2020 Berz

# Today, Diagnosis and Monitoring of Cancer Involved in the CNS is Inadequate

## Current clinical standard of care to determine CNS involvement

- Clinical signs and symptoms
- Radiologic imaging (CT/MRI)
- CSF cytology (microscopic evaluation of CSF by pathologist)



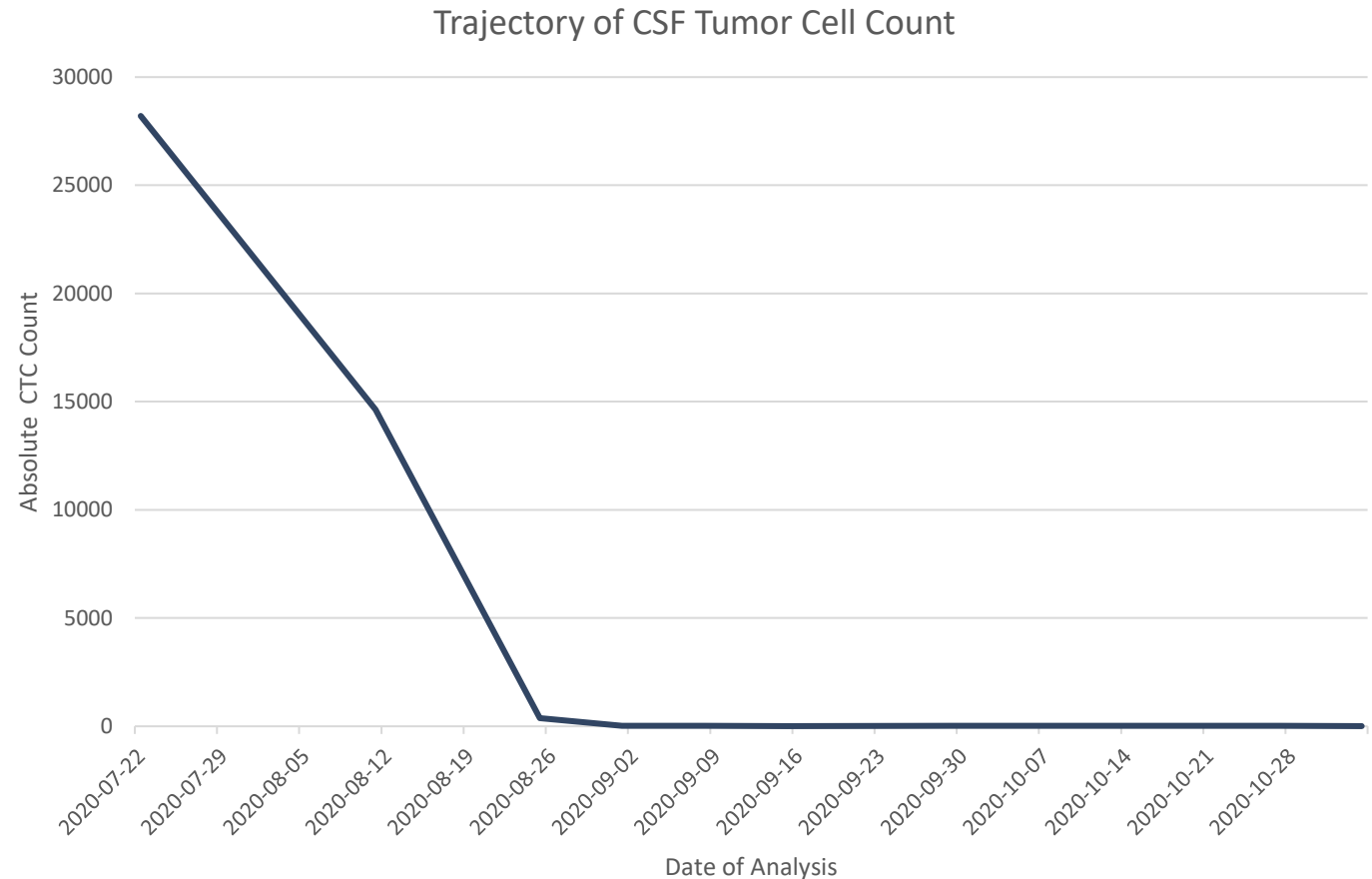
Here is where Biocept is being ordered

## Cytologic evaluation alone of CSF is not optimal for diagnosis or treatment monitoring

- Often indecisively reported as “few atypical cells or pauci-cellular sample,” inadequate for dx, etc.
- Established performance is sub-optimal and is unreliable for supporting treatment decisions
- NCCN guidelines reflect need to attempt cytology 3xs
- Qualitative result only (yes/no/maybe); inadequate for therapy monitoring

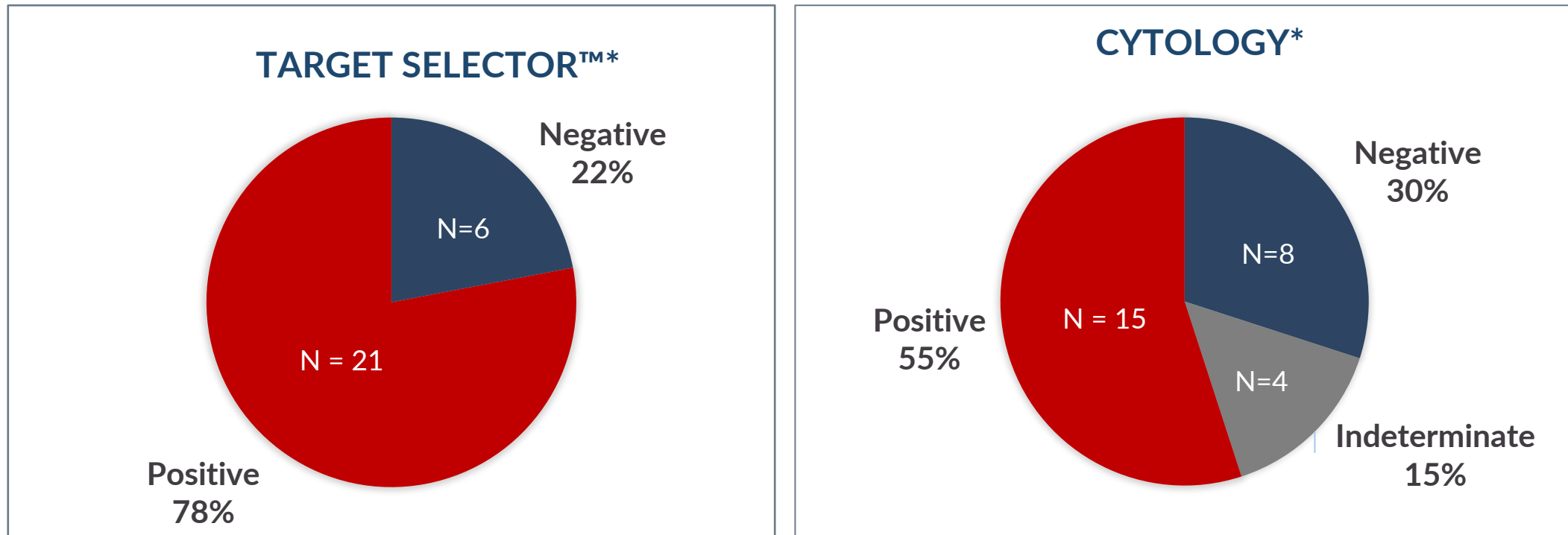
# Case Study: Patient with Metastatic Breast Cancer Spread to Brain

- Woman in 40s, history of **breast cancer, now with neurologic symptoms** and imaging c/w LMD
- Systemic treatment started in July 2020
- Monitored with Biocept tests
- Continues to exhibit response to treatment



## **CNSide™** Quantitative Tumor Cell Detection Compared to CSF Cytology

Tumor cell counts detected with Biocept are much higher and feasibility data suggests CNSide is more sensitive than cytology



\*Source: Berz et al, Poster, IASLC, 2020



# The 4C Study (Registry Trial)

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Registry Study – CSF-CTCs/ctDNA vs Clinical Standard of care (Cytology, Imaging, Clinical Evaluation)

- Design: Non-interventional trial evaluating performance of Target Selector™ compared to Clinical Imaging, Cytology, Clinical Evaluation in patients with suspected LMD in various indications
- Sponsor: Biocept
- Objective: Compare CNSide with Cytology in predicting clinical outcome
- Indications: Non-Small Cell Lung Cancer, Breast Cancer, Melanoma, Lymphoma
- Type of study: Registry study to support clinical utility
- N= 200
- Duration: 18 months

**Our goal...clinical adoption to become standard of care in NCCN guidelines**



# Diagnosis & Monitoring of CNS is >\$1B Market Opportunity

- **Large Unmet Need**
  - 150,000 – 200,000 brain metastases annually<sup>1</sup>
  - Top 2 cancers in LMD are lung (50%) and breast (15%)<sup>2</sup>
- **Target Market**
  - Neuro-oncologists: early adopters (380)
  - Medical Oncologists (>12,000)
  - **Blood and CSF orders from same client base**
- **Goal to Gain High Value Reimbursement >\$3,000 per assay**
  - Currently receive ~\$1,700 per specimen
  - Monitoring estimate >2.5 tests for 50% of patients

**Total Market  
Diagnosis and  
Therapy  
Selection  
\$450-\$600M<sup>3</sup>**

**Total Market  
Therapy  
Response,  
Disease  
Monitoring  
\$500-\$750M<sup>3</sup>**

<sup>1</sup><https://training.seer.cancer.gov/brain/tumors/>

<sup>2</sup>ASuh JH, Kotecha R et al., Nat Rev Clin Oncol 2019

<sup>3</sup>Based on annual brain metastases and Biocept's estimates on test volumes and price per test

# Neuro-Oncology Strategy to Become Standard of Care

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## Engage Key Opinion Leaders

- Steering committee established and being expanded with KOLs from leading institutions such as Northwestern, JWCI, Stanford, Penn State, Mayo and others

## Establish Clinical Validity for Multiple Indications

- Generate data to support the accurate and reliable detection of tumor cells in CSF for LMD diagnosis compared to cytology (standard of care) to support marketing authorization as a Class II IVD

## Establish Clinical Utility

- Registry study data to demonstrate improved patient health outcomes to support adoption and reimbursement

## Strategy to Gain FDA Breakthrough Designation

- Continue to expand data set following recent FDA denial of initial submission
- Test continues to be marketed as a lab developed test (LDT) in CLIA-certified, CAP-accredited lab

## Grow Market Share

- Sales focused on expanding neuro-oncology market then broader oncology market
- Expand menu to other tumor types and primary brain tumors

## Develop New Standard of Care

- Submit a *De Novo* Classification Request with clinical validation data to support a Class II IVD
- Publish multi-institutional data derived from observational clinical studies and support more IVD claims
- Gain adoption in **NCCN guidelines by 2023** for LMD diagnosis and therapy response monitoring

# Health Plan Access Continues to Expand with Third-Party Contracts

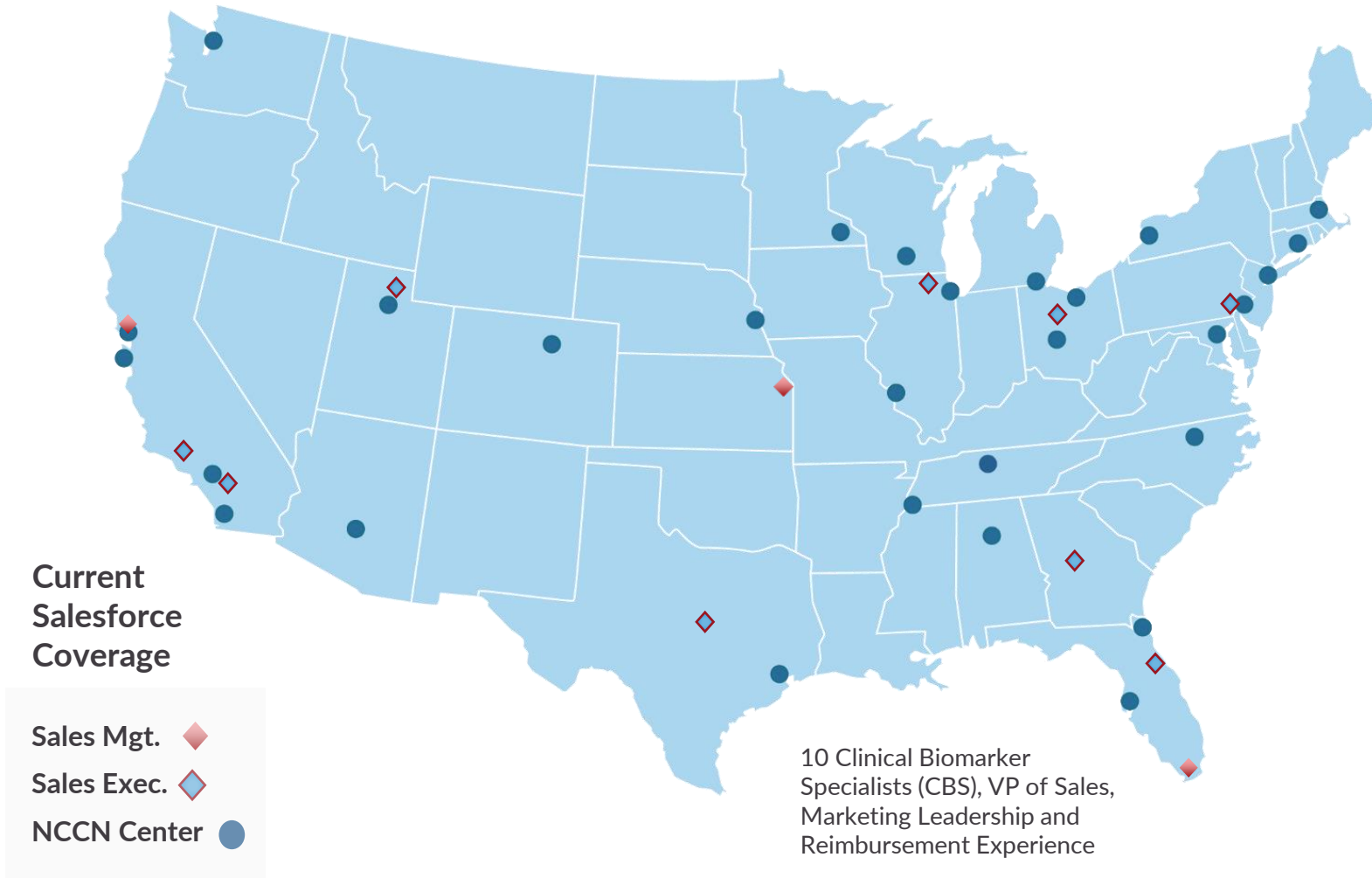


BlueCross  
BlueShield



- Managed Care agreements in place covering >200 million lives
- Dedicated managed care leadership with years of experience from GE, LabCorp and others
- Payors have positive coverage for biomarkers listed in guidelines
- Aligns with goals of healthcare reform
- Improved outcomes while reducing costs
- Utilize established CPT codes
- Expecting reimbursement for NGS panels developed with Thermo Fisher by 2021 year end

# Commercial Strategy



Over **2 dozen** leading cancer centers ordering



testing from Biocept

## Commercial Team

- Oncology Experienced
- Neuro-oncology Focus
- Deep Market Knowledge
  - National Accounts
  - Market Access

# Commercial Collaborations



- Executing on strategy to contract with major cancer treatment institutions, GPOs, and distributors
- Increasing patient access
- Accelerating adoption of liquid biopsy
- Leveraging sales and marketing resources by increasing awareness of Biocept's liquid biopsy platform within large health systems
- Roll out new tests and service offerings including molecular pathology partnering model (i.e., Empower TC™)
- Gaining value from data

# Biocept IP Portfolio – 71 Patents Issued Worldwide

|   |  |                                  |
|---|--|----------------------------------|
| <p><b>Family 1</b></p> <p>MicroChannel for CTC Capture</p> <ul style="list-style-type: none"> <li>Recovery of Rare Cells using Microchannel</li> <li>Device for Cell Separation &amp; Analysis</li> </ul>   | <p>1) Issued in US (2), China (3), Germany, Spain, France, Great Britain, Hong Kong (2), Italy, Japan, Korea</p> <ul style="list-style-type: none"> <li>Pending in Australia</li> </ul> <p>2) Issued in US</p>   | <p>Expire<br/>2025-<br/>2027</p> |
| <p><b>Family 2</b></p> <p>CTC Capture With Antibody Cocktail</p> <ul style="list-style-type: none"> <li>Subfamily 1 – Devices &amp; Methods of Cell Capture Analysis</li> <li>Subfamily 2 – Method and Reagents for Signal Amplification</li> </ul>   | <p>1) Issued in US (3), Australia (2), Belgium, Canada, China, Switzerland, Germany (2), Spain, France (2), Great Britain (2), Hong Kong, Ireland, Italy (2), Japan (4)</p> <p>2) Issued in US, Belgium, Canada, China, Germany, France, Great Britain, Hong Kong, Ireland, Italy, Japan</p>                       | <p>Expire<br/>2030-<br/>2032</p> |
| <p><b>Family 3</b></p> <p>Collection Tube</p> <ul style="list-style-type: none"> <li>Use of DU for Anti-Clumping of Biological Sample</li> </ul>  | <p>1) Issued in US</p>   | <p>Expire<br/>2031</p>           |
| <p><b>Family 4</b></p> <p>Switch-Blockers for ctDNA Analysis</p> <ul style="list-style-type: none"> <li>Methods for Detecting Nucleic Acid Sequence Variants</li> </ul> <p>Primer-Switch for Nucleic Acid Analysis</p> <ul style="list-style-type: none"> <li>Divisional – Methods for Rare Genetic Variant Detection and PCR Amplification Improvements</li> </ul> | <p>1) Issued in US, Australia (2), Belgium, Brazil, China, Canada, Germany, France, Great Britain, Hong Kong, Ireland, Italy, Japan (2), Korea</p> <p>2) Issued in US, Australia and South Korea</p> <ul style="list-style-type: none"> <li>Pending in Japan, China, Canada, Hong Kong,, Brazil, and EU</li> </ul> | <p>Expire<br/>2031</p>           |

# Leadership Team

## Michael Nall President & CEO

- 25+ years in healthcare sales, marketing and commercial operations
- 20+ years in cancer diagnostics and genomics
- 7 years as Biocept CEO
- Most recently General Manager N. American Sales and Marketing for Clariant – a GE Healthcare Company

## Tim Kennedy COO & CFO

- 30+ years of financial experience, 25+ years in the clinical diagnostics industry
- Instrumental in 2.1B restructuring of Millennium Health, a privately-held urine drug lab
- Numerous senior management positions – helped transform PLUS Diagnostics into largest independent U.S pathology lab; merged National Health Labs and Roche Biomedical Labs to form LabCorp

## Michael Dugan, MD CMO and Medical Director

- Board certified Pathologist
- Univ of AZ, Yale, UCLA
- Numerous publications, serves on CAP committees
- Leadership positions at Exact Sciences, Clinical Genomics, Quest, Genzyme and others

## Lyle Arnold, PhD SVP, Chief Scientist

- Senior R&D leadership at Gen-Probe, Incyte Genomics, Genta
- Founder/ Co-founder Oasis Biosciences, Molecular Biosystems, Aegea Biotechnologies
- Former faculty member, UCSD School of Medicine and member, UCSD Cancer Center
- 47 issued US and more than 140 issued and pending patents worldwide

## Michael Terry SVP, Corporate Development

- 25+ years commercial leadership experience in molecular diagnostics and med-tech companies
- Former GE Healthcare executive, certified in Six Sigma
- Recent experience in liquid biopsy field; EVP commercial operations at both Sequenom and Trovogene





# Biocept is Guided by a Board of Visionaries & Scientific Influencers

## Board of Directors

**Samuel D. Riccitelli**  
Chair

**Marsha A. Chandler, PhD**  
Director, Chair of Nominating and  
Governance Committee

**Bruce E. Gerhardt, CPA**  
Director, Chair of Compensation  
Committee

**David F. Hale**  
Director and Past Chair

**Antonino Morales**  
Director

**Michael W. Nall**  
Director, President & CEO

**Ivor Royston, MD**  
Director, Chair of Science and  
Technology Committee

**Linda Rubinstein**  
Director

**M. Faye Wilson, CPA, MBA**  
Director, Chair of Audit Committee

## Clinical Advisory Board

**David Berz, MD, PhD**  
Beverly Hills Cancer Center  
Chief Medical Officer – Valkyrie  
Pharmaceuticals  
Beverly Hills, California

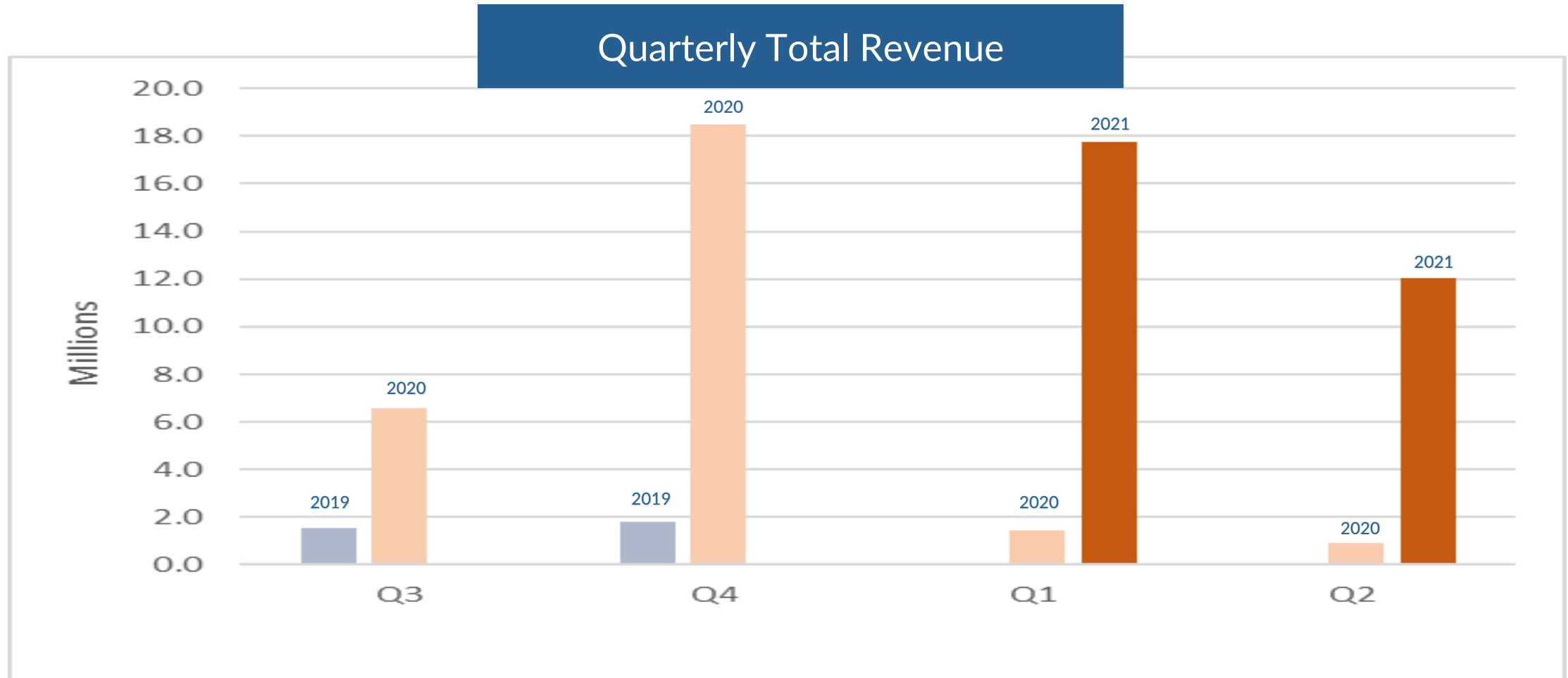
**Santosh Kesari, MD, PhD**  
Chair, Dept. of Translational Neuro-  
oncology and Neurotherapeutics, John  
Wayne Cancer Institute, Santa Monica,  
California

**Priya Kumthekar, MD**  
Associate Professor of Neurology  
(Neuro Oncology) and Medicine  
(Hematology and Oncology)  
Northwestern Medicine  
Feinberg School of Medicine  
Chicago, IL

**Lee Schwartzberg, MD**  
Chief, Division of Hematology  
Oncology; Professor of Medicine,  
University of Tennessee



# Deploying Capital To Fuel Growth



3Q 2020 revenues reflect the beginning ramp-up of COVID-19 test

**\$19.4 million in cash and equivalents at 6/30/21**

# Corporate Priorities

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1

Position CNSide as standard of care for the diagnosis and monitoring for CNS involvement

2

Continue to expand commercial adoption of CNSide for tumor cell detection in CSF

3

Initiate CNSide clinical validity and utility studies leading to FDA IVD approvals & NCCN Guidelines

4

Secure Medicare high-value coverage for Target Selector™ Lung NGS Panel and other assays

5

Grow sales of Target Selector™ liquid biopsy kits and CEE-Sure blood collection tubes

6

Enter into additional strategic commercial and technology partnerships

7

Commercialize quantitative COVID-19 assay developed in collaboration with Aegea Biotechnologies

8

Expand data set to support Breakthrough application