

## **Corporate Overview**

July 2022

Nasdaq: BIOC www.biocept.com

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## **Forward-Looking Statements**

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.

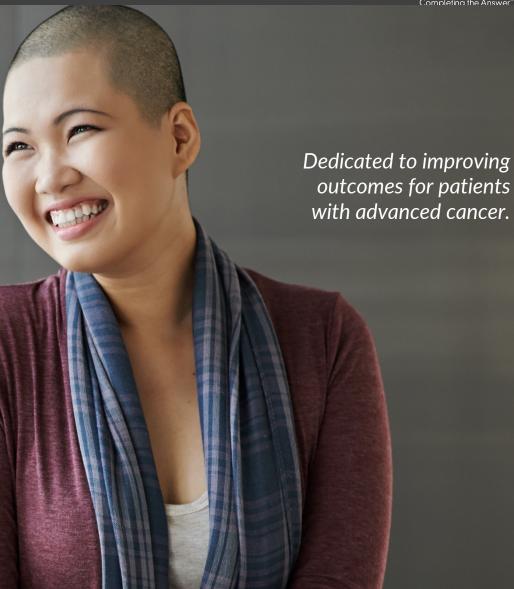
Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. For details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



## **Investment Highlights**

- ➢ Pioneering proprietary CNSide<sup>™</sup> assay using cerebrospinal fluid (CSF) to test for cancer involvement in the central nervous system (CNS); initial U.S. market opportunity of \$1.2B
- Expanding CNSide usage among neuro-oncologist KOLs;
   23 of 64 NCI-Designated Cancer Centers using CNSide
- Pursuing CNSide standard of care status to support broader adoption and higher reimbursement by generating clinical data through FORESEE and company-sponsored investigator studies
- Targeting collaborations with biopharma partners using CNSide assay to support therapeutics clinical trials
- Serving the community and supporting our cash position with COVID-19 RT-PCR testing



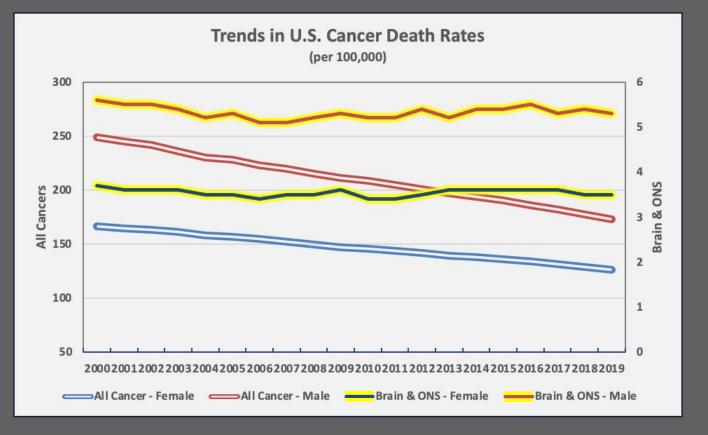
## **Neuro-Oncology**

Market Overview



## **Recent Trends in U.S. Deaths Due to Cancer**

- Cancer deaths in aggregate declined >25% from 2000 to 2019 due to improved screening, diagnosis and prevention, lower smoking rates, and improved treatments
- Deaths due to cancer of the brain and other nervous system (ONS) have unfortunately remained stable
- Metastasis accounts for 90% of all solid tumor cancer mortality<sup>1</sup>



1. Taftaf, R. et al. Nature Communications 12, 4867 (2021).

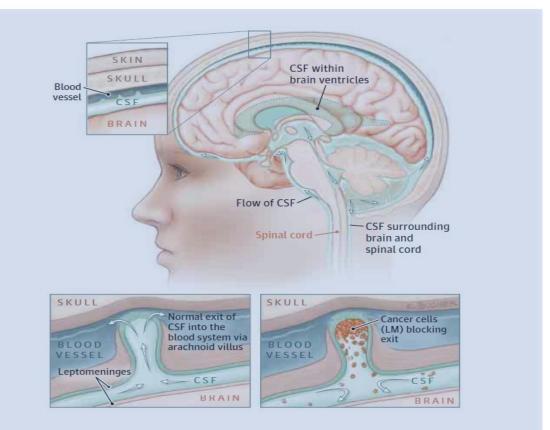
- Source:
- American Cancer Society
- NCI SEER Statistics



## Leptomeningeal Metastases (LM)

- Cancer cells in the subarachnoid space/CSF
- > Solid and Hematologic malignancies
- Symptoms:
  - > High intracranial pressure and/or spinal cord compression
  - Cranial nerve symptoms
  - > Spinal cord and nerve root involvement causing extremity weakness, paresthesia and/or pain.

Frequency of LM by Solid Tumor Type <sup>1-4</sup>		
Breast cancer	12-35%	
Lung cancer	10-26%	
Melanoma	5 - 25%	
Gastrointestinal	4 - 14%	
Unknown Primary	1-7%	



The **most common** cancers that develop LM are breast cancer, lung cancer, melanoma, and GI malignancies.

However, **any malignancy** may seed the leptomeningeal space.



## **LM Overall Solid Tumor Incidence**

**3-8%** of solid tumor patients will be diagnosed with LM during the course of their illness<sup>1-3</sup>

**20%** of cancer patients demonstrated LM at autopsy<sup>4-8</sup>

**40%** of patients positive at autopsy had negative CSF cytology prior to death<sup>4,5</sup>

On average, leptomeningeal metastasis is detected **3.5X** more frequently at autopsy than it is diagnosed clinically

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## **LM Unmet Clinical Needs**

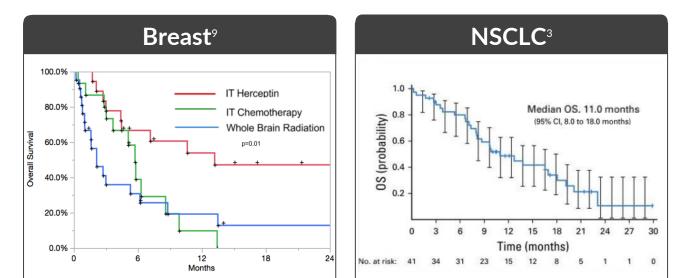
#### ➤ Underdiagnosed<sup>5-8</sup>

- MRI: low positive predictive value
- > Cytology: low overall sensitivity

MRI Imaging <sup>5</sup>	CSF Cytology <sup>6,7,8</sup>
Sensitivity 75%	Sensitivity 50%
Specificity 77%	Specificity 95%

#### ➤ Undertreated<sup>1,2,3,4,9</sup>

- > Average survival w/o therapy: 4-6 weeks
- > Average survival w/ therapy: 2-4 months
- Average survival w/ targeted therapy: 11-19 months



Batool A. Leptomeningeal Carcinomatosis.
 StatPearls; 2022
 J Neurooncol. 2013 Sep;114(2):229-35.
 J Thorac Oncol. 2012 Feb;7(2):382-5.
 Ann Oncol. 2020 Oct;31(10):1397-1404.

Int J Cancer. 2015 Jan 1;136(1):162-71.
 Arq Neuropsiquiatr. 2013 Sep;71(98):677-80.
 Semin Oncol. 2009 Aug;36(4 Suppl 2):S35-45.
 Neurology. 1979 Oct;29(10):1369-75.
 Breast Cancer Res Treat. 2019 Jun;175(3):781-788

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## **2022 Independent Market Research – U.S.**

CNSide TAM (# of patients/year)	Literature Sources	Market Research
<b>Diagnosis TAM</b> parenchymal brain metastases (rule out LM)	112,000	101,800
Treatment/Monitoring TAM parenchymal brain metastases	59,400	54,000
<b>Diagnosis TAM</b> LM	41,100	56,700
<b>Treatment/Monitoring TAM</b> LM	21,800	30,100
TOTAL	234,300	242,600



## **CNSide**

Assay Technology, Attributes, and Data



# **CNS**ide First commercially available real time method to measure biomarker status of CNS

- Intended to determine the presence, quantity, and characterization of malignant cells in CSF
- Currently performed primarily for suspicion of or diagnosis for LM

CLIA-Validated Test for Metastatic Carcinomas\*

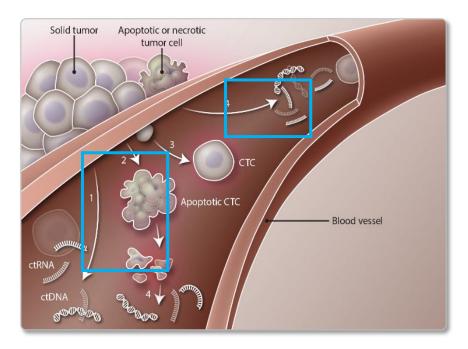
- ✓ Sensitivity: 92%
- ✓ Specificity: 100%

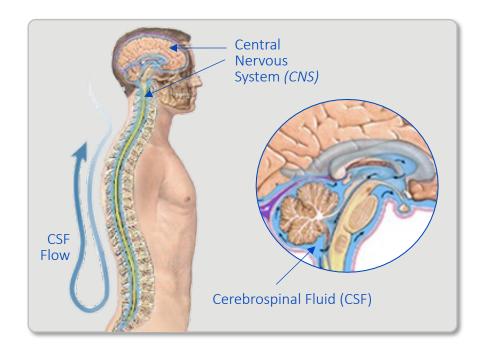
\*(N=79 Clinical CSF Samples<sup>1</sup>)



## **CNSide Identifies Biomarkers & Drug Targets in CSF**

- Tumor cells circulating in blood (CTCs) can infiltrate the CSF (a cul-de-sac) forming the basis for CNS metastasis
- ctDNA and ctRNA derived from tumors can be shed into blood or CSF as cells die, but they do not confirm metastasis
- > Biocept analyzes tumor cells and cell-free DNA in CSF for diagnosis, biomarker status, and monitoring





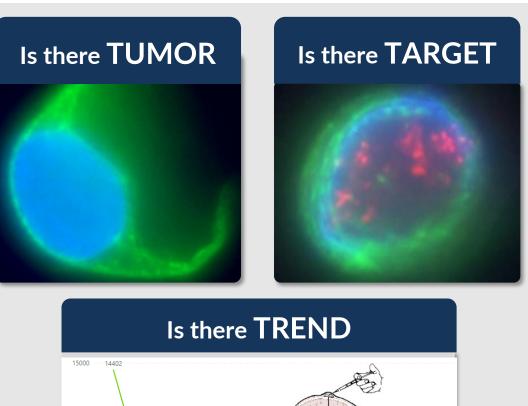


### **CNSide Addresses Several Unmet Clinical Needs**

**Detection** of LM can be improved using cell capture technology

Therapeutic **target selection** can be informed by multiplexing cellular and molecular assays on single samples

Quantifying results for longitudinal observations allows for disease **monitoring** 

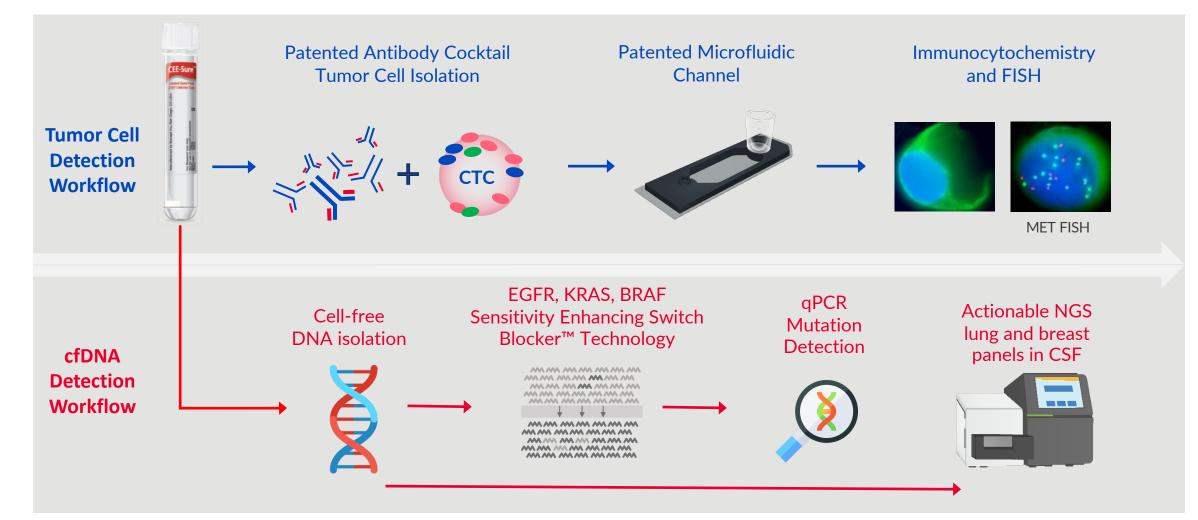


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## **Biocept CNSide Proprietary Technology and Workflow\***



\* The Patented CEE-Sure<sup>™</sup> sample collection tube can be used for either workflow



## **Biocept IP Portfolio – 42 Patents Issued Worldwide**

<ul> <li>Family 1</li> <li>MicroChannel for CTC Capture</li> <li>Recovery of Rare Cells using Microchannel</li> <li>Device for Cell Separation &amp; Analysis</li> </ul>	Issued in US (3), China (3), EU PTO, Hong Kong (3), Japan, S. Korea, Canada	Expire <b>2025-2027</b>
<ul> <li>Family 2</li> <li>CTC Capture With Antibody Cocktail</li> <li>Subfamily 1 - Devices &amp; Methods of Cell Capture Analysis</li> <li>Subfamily 2 - Method and Reagents for Signal Amplification</li> </ul>	Sub 1) Issued in US (3), Australia (2), Canada, China, EU PTO (2), Hong Kong, Japan (4) Sub 2) Issued in US, Canada, China, EU PTO, Hong Kong, Japan	Expire <b>2030-2031</b>
<ul><li>Family 3</li><li>Collection Tube</li><li>Use of DU for Anti-Clumping of Biological Sample</li></ul>	1) Issued in US	Expire <b>2031</b>
<ul> <li>Family 4 – In licensed from Aegea</li> <li>Switch-Blockers for use in real time PCR on CSF samples</li> <li>Methods for Detecting Nucleic Acid Sequence Variants</li> </ul>	1) Issued in US, Australia, EU PTO, Brazil, China, Hong Kong, Japan , S. Korea	Expire <b>2032</b>



## **CNSide Publications, Posters, and Abstracts**

#### **Eight Published CNSide Documents to Date**



Biocept Completing the Answer

# AAN April 2022: Longitudinal Use in Multiple Tumor Types & Longitudinal Genetic Heterogeneity of HER2 Status

Saint John's Health Center Providence

Using Cerebrospinal Fluid Tumor Cell (CSF-TC) Assays to Track Disease Burden and Treatment Response in Patients with Leptomeningeal Metastasis

Akanksha Sharma,<sup>1</sup> Nathan Sweed,<sup>2</sup> Barbara Blouw,<sup>2</sup> Deanna Fisher,<sup>2</sup> Kaitlyn Armijo,<sup>2</sup> Steven Hsiao,<sup>2</sup> Anna Natasha,<sup>2</sup> Shiyi Hua,<sup>2</sup> Pericles Corkos,<sup>2</sup> Tony Pircher,<sup>2</sup> Naveed Wagle, <sup>1</sup>Joca Carrillo, <sup>2</sup> Minh Ryuyen,<sup>1</sup> Judy Truong,<sup>3</sup> Michael Dugan,<sup>2</sup> Santosh Kesari<sup>1</sup> <sup>1</sup>Department of Translational Neurosciences, Pacific Neuroscience Institute/Providence Saint John's Cancer Institute, <sup>1</sup>Biocept, Inc

#### Background

- Leptomeningeal metastasis (LM) is diagnosed in approximately 5% of patients with metastatic cancer and has a dismal prognosis (4-6 weeks, untreated)
- Imaging, clinical exam, and cytology all have limited capability for diagnosis and disease monitoring of LM

#### Methods

- Five (5) cases of LM were diagnosed and followed using the Biocept<sup>\*\*</sup> CNSide<sup>\*\*</sup> platform
   For each specimen, approximately 6-8 mL of CSF was obtained and transported using the CNSide assay's proprietary tubes
- Each specimen underwent CSF-TC capture, immunocytochemistry (ICC), and (when applicable) fluorescence in situ hybridization (FISH)

#### Patient Demographics

Tucatinib, IT Methotrexate, Breast 1 F 40 (HER2+) Cytarabine, IT Trastuzumab (Added), 17 mos IT Pemetrexed (Added) Melanom IT Cytarabine, IT Thiotepa 10 mos 2 M 70 (PD-11+ Esophagea (HER2+) IT Topotecan 3 M 63 2 mos IT Trastuzumab (Added) Breast IT Cytarabine IT Methotrevate 4 F 59 7 mos (ER+, PR+ Neuroendocrin 5 M 76 Capecitabine, Temozolomi 5 mos Carcinoma OS - Overall Survival, IT - Intrathecal

Learn more about the CNSide assay

#### **CNS**ide

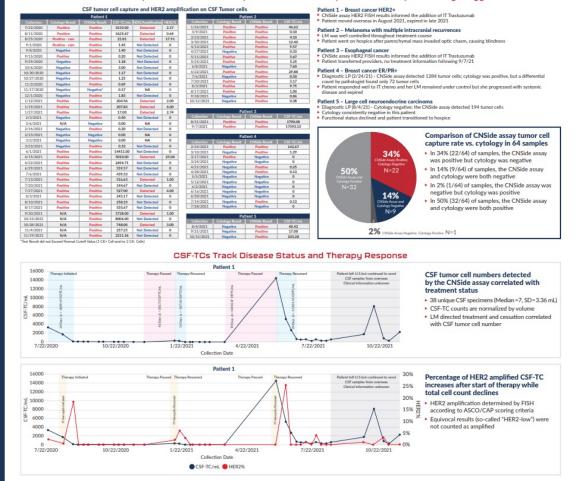
#### Conclusions

The CNSide assay shows significant advantages in monitoring treatment response and disease course in LM

#### The CNSide assay identifies

- biomarkers in LM patients for which targeted therapeutic interventions can significantly improve neurological symptoms and survival
- Additional longitudinal trials to assess the utility of this platform for LM patients are warranted

Biocept Completing the Answer"

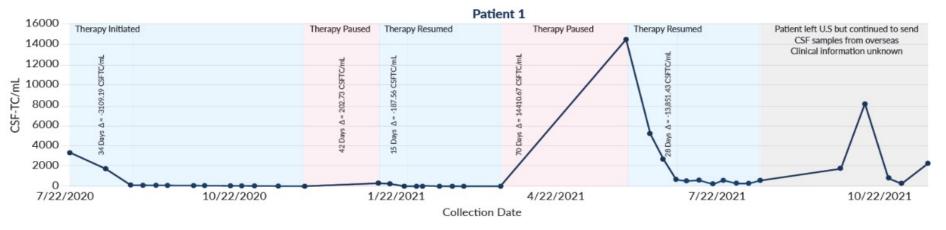


CSF-TC Capture Demonstrates Improved Tumor Cell Capture Rate Compared To Cytology

## Case Study Demonstrating CNSide<sup>™</sup> Utility<sup>1</sup>

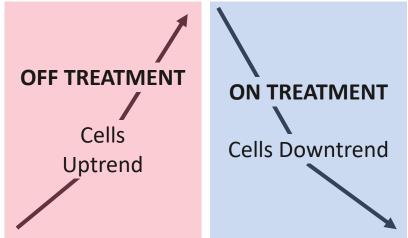
#### 40-year-old Female

- Breast Cancer
   Primary Tumor
- Diagnosed with LM



#### CSF tumor cell numbers detected by the CNSide assay correlated with treatment status

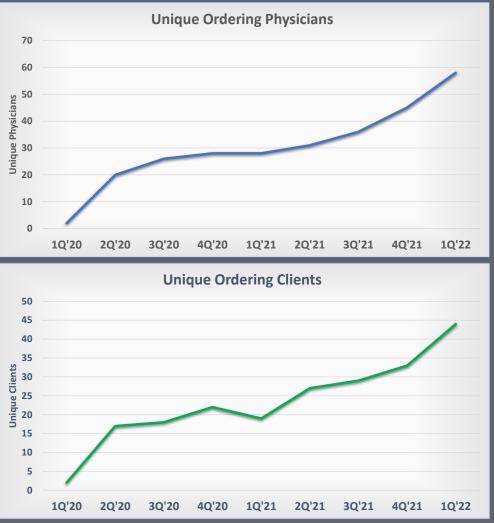
- 38 unique CSF specimens (Median = 7, SD = 3.36 mL)
- CSF-TC counts are normalized by volume
- LM directed treatment and cessation correlated with CSF tumor cell number





## **Promising Early Commercial Adoption of CNSide**





## **FORESEE Clinical Trial**

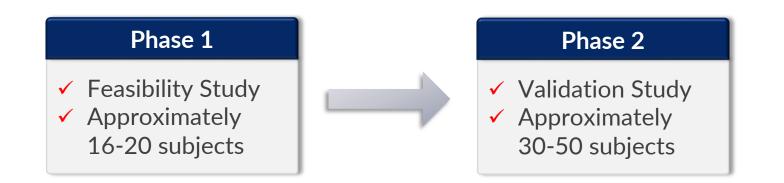
A Prospective, Multi-Institution Study Led by Northwestern University



## Biocept's Clinical Trial - FORESEE Study (NCT#: NCT05414123)

**Objectives:** 

- To determine the impact of CNSide in managing Leptomeningeal Metastasis in patients with Breast or Non-Small Cell Lung Cancer
- Assess correlation of CSF Tumor cells with clinical response
- > Evaluate CNSide in helping to determine course of treatment
- Study design:



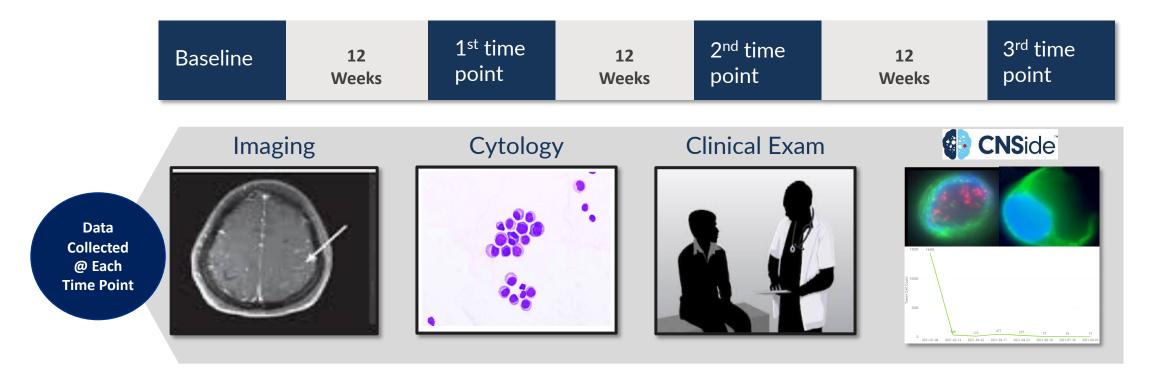


Clinical adoption to become standard of care



## **FORESEE Trial Schema**

- > CNSide, imaging, CSF cytology and clinical results collected at baseline and 3 consecutive time points
- > Tumor cell detection by CNSide will be correlated with response to treatment
- > Impact of CNSide on treatment decision making will be assessed via physician questionnaire



## **The Opportunity**

Building shareholder value with CNSide



## **CNSide Commercial Strategy**



3

#### Expand CNSide Usage Among Thought-Leaders

 Generate further engagement, experience, and advocacy for CNSide with this small core of experts and leaders

#### **Develop the Market**

- Expand adoption through publication of FORESEE and company-sponsored investigator clinical utility results, KOL presentations, and exceptional customer experience
- > Expand to additional neurological indications

#### Gain high-value reimbursement of >\$4,000 per assay

- > Near-term expansion of high-value biomarker coverage
- Transition to global coding and payment at proprietary pricing as clinical utility evidence develops

#### Inclusion in NCCN Guidelines for LM

- Support repeat testing for therapy response monitoring
- Expand adoption to medical oncologists

#### **Target Market**

- Neuro-oncologists and thought leaders for early adoption (<1,000)</li>
- Medical Oncologists (>12,000)

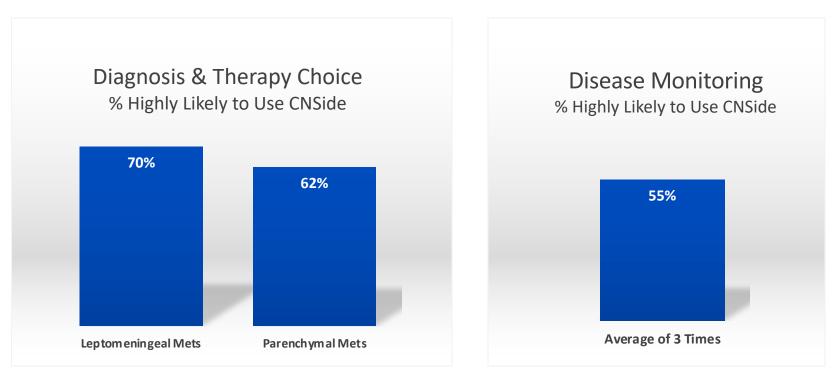
**Commercial Focus on Product Development, Expanded Clinical Use, and Price Enhancement** 



## **2022 Quantitative Market Research**

Key Survey Findings from 150 Medical Oncologists

A majority are highly likely to use CNSide for diagnosis and therapy choice and more than half are highly likely to use CNSide for monitoring LM and parenchymal brain metastases





## **Biocept in the CSF Liquid Biopsy Market**

#### Leptomeningeal Metastasis

Establish CSF beachhead in area with critical unmet needs

- Significantly advance patient care and management
- >200,000 with CNS involvement<sup>1</sup>

#### **PBM & Gliomas**

Expand to other neuro-oncology indications

- > Parenchymal brain metastases
- Primary brain tumors

#### **3** Brain Metastases Screening

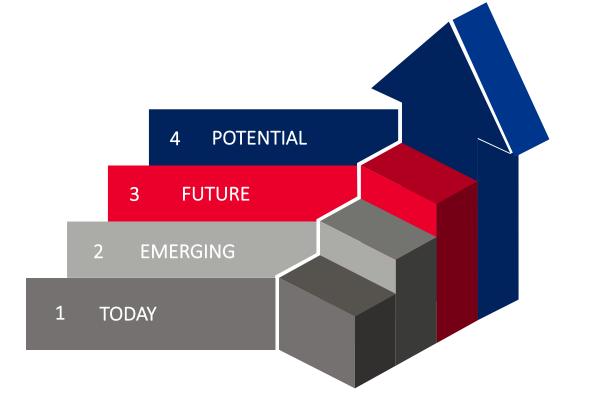
Enable earlier detection

- Emerging evidence of which high-risk primary solid tumors are associated with metastases
- Establish clinical evidence of utility

#### Other neurological diseases

CSF analysis as a window into other CNS disease processes<sup>2</sup>

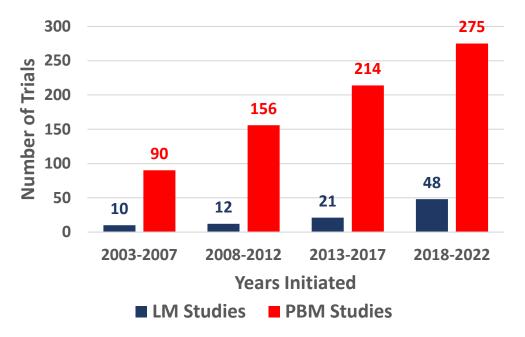
- Especially where cellular process are involved
- Potential for neurodegenerative disease



1. https://www.cancernetwork.com/view/management-brain-metastases https://www.cancer.gov/about-cancer/understanding/statistics

2. Busse et al, Brain Behav Immun Health; V.14;2021 Jul

## **CNSide Biopharma Services – The Market Opportunity for CNS Metastases**



#### CNS Metastases Studies Initiated from 2003-2022\*

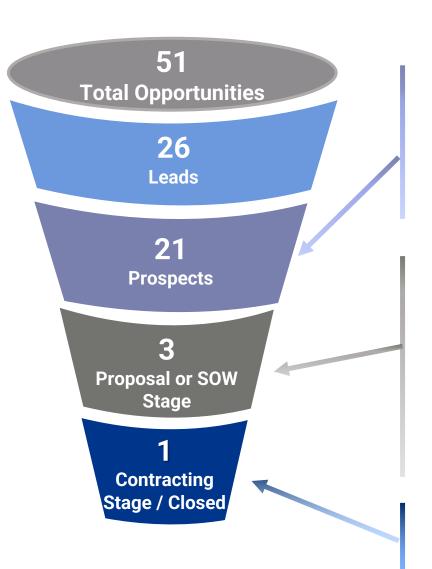
#### Key Catalysts for Growth

- ➤ Incidence of brain metastases is rising as result of increased survival and improved prognosis (~30% of patients) → Data from autopsy cohorts suggest incidence much higher<sup>1</sup>
- Biopharma is investing heavily in CNS metastases therapeutic development <u>– 100 programs initiated in past 5 years</u>
- LM-focused studies have more than tripled in the past 15 years
- Advancements in local and systemic therapies have improved median survival following initial CNS metastasis treatment<sup>2,3</sup>
- Cancer Moonshot Initiative & ASCO recommendations<sup>4</sup>: FDA is working with sponsors to improve eligibility criteria of CNS metastases
  - > Urges metastatic patient inclusion in early-phase studies
  - Recommends inclusion of LM in early-phase trials of drugs with anticipated CNS activity
- ➤ Most CNS metastasis studies are in early phases → gives Biocept the opportunity to incorporate CNSide in protocol
- Parenchymal CNS metastases comprise the largest segment Biocept IST trials will establish performance of CNSide in these populations and document new intended uses

<sup>\*</sup> Information obtained from http://www.clinicaltrials.gov

### **Biopharma Neuro-Oncology Services Pipeline**





Opportunity	Stage	
World Leading Cancer Inst. Breast Research Group	New Prospect!!	
Top Tier Biopharma	New Prospect!!	
Top Tier Biopharma	New Prospect!!	
Major Cancer Research Network BC-IPBM Study	SOW submitted	
Emerging Biopharma cMet Glioma Study	SOW Submitted	
Emerging Biopharma NTRK LC-IPBM Study	Proposal Stage	
<b>Plus Therapeutics</b> 186RNL LM Study	Contract Closed 1 <sup>st</sup> Patient Enrolled	



## Leveraging Expertise to Provide COVID-19 RT-PCR Testing

#### >920,000+ COVID-19 samples received for SARS-CoV-2 testing since launch in June 2020

- > 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</p>
- Performed with 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

#### Agreement with California Community Colleges

- Providing access to testing as students return to in-person classes
- Collaboration to provide a system for tracking and managing COVID-19 testing requirements and test results



## **COVID-19 Volume Drives Revenue Growth, Reducing Cash Burn**

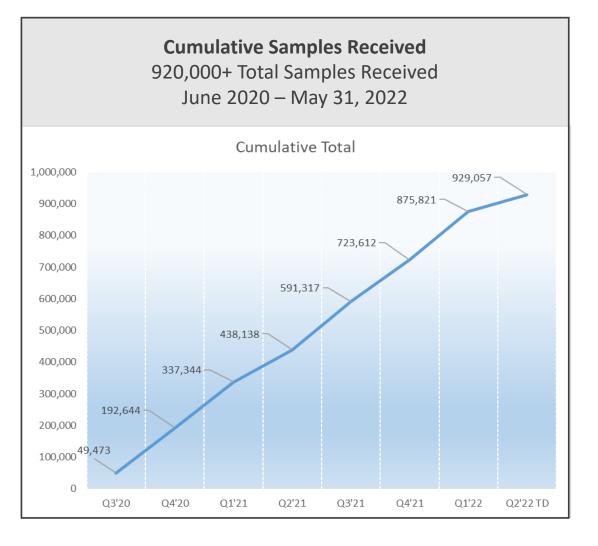
#### **Medicare Reimbursement**

> \$100 per test

#### Lab Capacity to Meet Demand

- COVID-19 volume drove increased capacity
- Automation and investment in additional molecular technologies to meet demand
- Ability to ramp to >10,000 tests per day

#### Supports Investment in Core Neuro-Oncology Business



## **The Team**



## **Leadership Team**

<b>Sam Riccitelli</b> Chair, Interim President & CEO	<ul> <li>Seasoned executive with 35+ years medical device &amp; diagnostics experience</li> <li>Serial oncology diagnostics entrepreneur</li> <li>Former COO at Genoptix, Inc.</li> </ul>	GENOPTIX MEDICAL LABORATORY
<b>Antonino Morales, CPA</b> Director, Interim CFO	<ul> <li>Broad leadership experience in the US and Latin America with Fortune 100 and early-stage start-up companies</li> <li>Senior executive/consulting roles with Citibank, Bank of America, Arthur Andersen, McDonald's, and Mazda</li> <li>University of Southern California; Licensed California CPA</li> </ul>	BANK OF AMERICA 🦘
Philippe Marchand, PhD COO	<ul> <li>20+ years experience in oncology diagnostics and biopharma industries</li> <li>Proven operations and technology track record as an executive</li> <li>Extensive experience in rare cell isolation and analysis technologies</li> </ul>	
<b>Michael Dugan, MD</b> CMO and Medical Director	<ul> <li>Board certified Pathologist</li> <li>Univ of AZ, Yale, UCLA</li> <li>Numerous publications, serves on CAP committees</li> <li>Leadership positions at Exact Sciences, Clinical Genomics, Quest, Genzyme and others</li> </ul>	
Darrell Taylor, JD SVP, CLO & CCO	<ul> <li>20+ years of extensive legal expertise focusing on healthcare transactional, regulatory, and compliance matters</li> <li>15+ years on the provider side at LabCorp of America and other clinical and research laboratories</li> <li>Formerly with global law firm DLA Piper and in-house at Abbott Labs, AbbVie, and Sorrento Therapeutics</li> <li>The University of Texas Medical Branch and Notre Dame Law School</li> </ul>	
<b>Michael Terry</b> SVP, Corporate Development	<ul> <li>25+ years commercial leadership experience in molecular diagnostics and med-tech companies</li> <li>Former GE Healthcare executive, certified in Six Sigma</li> <li>Recent experience in liquid biopsy field; EVP commercial operations at both Sequenom and Trovagene</li> </ul>	
<b>David Karlander</b> SVP, Commercial Operations	<ul> <li>25+ years of industry experience including extensive oncology experience</li> <li>Record of success in building and managing major diagnostics brands</li> <li>Former executive sales and marketing positions at Exact Sciences and Novartis' Genoptix Medical Lab</li> </ul>	mission bio



## **Board of Visionaries & Scientific Influencers**

### **Board of Directors**

- Samuel D. Riccitelli
   Chair, Interim President & CEO
- Marsha A. Chandler, PhD
   Director, Chair of Nominating and Governance Committee
- Bruce E. Gerhardt, CPA
   Director, Chair of Compensation Committee
- Antonino Morales, CPA Director, Interim CFO
- Ivor Royston, MD
   Director, Chair of Science and Technology Committee
- Linda Rubinstein Director
- M. Faye Wilson, CPA, MBA
   Lead Independent Director, Chair of Audit Committee

### Lead Clinical Advisors

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



## **Corporate Priorities**

1	2	3	4
Position Biocept as leader in emerging category of neurological tumor diagnostics	Establish CNSide as standard of care for diagnosis, identifying potential treatments and monitoring for CNS involvement	Initiate FORESEE clinical validity & utility study leading to guideline inclusion – 1 <sup>st</sup> patient enrolled in 3Q'22	Facilitate metastatic brain cancer therapy development by establishing revenue- generating biopharma company partnerships
5 Initiate company- sponsored investigator studies to support clinical validation and expanded use – 1 <sup>st</sup> study initiated by 2022-year end	6 Develop additional strategic commercial and technology partnerships to accelerate neurological diagnostic offerings	Publish CNSide clinical study results in respected, peer- reviewed journals	8 Establish MolDx reimbursement commensurate with findings from published clinical studies



## **Investment Highlights**

- Commercializing CNSide assay to test for cancer involvement in CNS; initial U.S. market opportunity of \$1.2B
- Expanding CNSide usage among neuro-oncologist KOLs
- Pursuing CNSide standard of care status to support broader adoption and higher reimbursement
- Targeting collaborations with biopharma partners using CNSide assay to support therapeutics clinical trials
- Serving the community and supporting our cash position with COVID-19 RT-PCR testing

