
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 14, 2022

BIOCEPT, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36284
(Commission
File Number)

80-0943522
(I.R.S. Employer
Identification No.)

9955 Mesa Rim Road, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 320-8200

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	BIOC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Beginning on July 14, 2022, members of the management team of Biocept, Inc. (the “Company”) may be providing presentation materials (the “Presentation”) to certain interested parties. A copy of the Presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1 are being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is being disclosed pursuant to Regulation FD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Presentation materials of Biocept, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIOCEPT, INC.

Dated: July 14, 2022

By: /s/ Samuel D. Riccitelli

Name: Samuel D. Riccitelli

Title: Interim President and Chief Executive Officer

Biocept™
Completing the Answer™

Corporate Overview

July 2022

Nasdaq: BIOC
www.biocept.com



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™ 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

Dedicated to improving outcomes for patients with advanced cancer.



A blurred photograph of a hospital hallway with blue walls and a person walking in the distance.

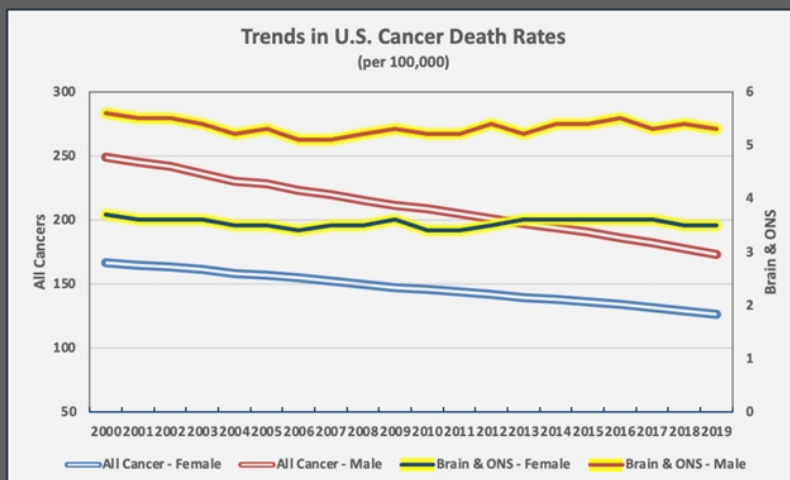
Neuro-Oncology

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 mortality¹

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

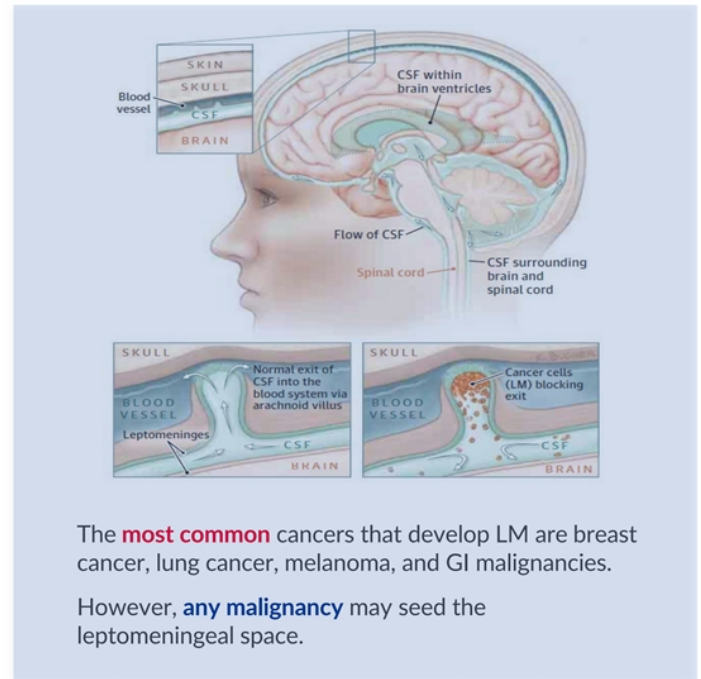


Source:
• American Cancer Society
• NCI SEER Statistics

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 ¹⁻⁴	
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 illness¹⁻³

20% of cancer patients demonstrated LM at autopsy⁴⁻⁸

40% of patients positive at autopsy had negative CSF cytology prior to death^{4,5}

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

LM Unmet Clinical Needs

➤ Underdiagnosed⁵⁻⁸

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



MRI Imaging⁵

Sensitivity
75%

Specificity
77%



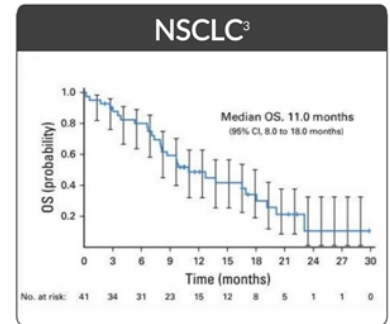
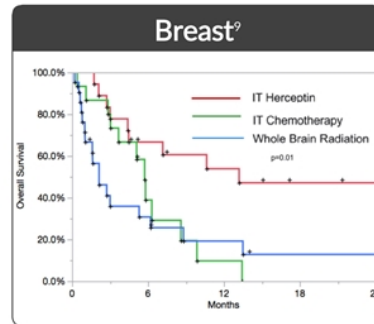
CSF Cytology^{6,7,8}

Sensitivity
50%

Specificity
95%

➤ Undertreated^{1,2,3,4,9}

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



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

5. Int J Cancer. 2015 Jan 1;136(1):162-71.
6. Arg Neuropsychiatr. 2013 Sep;71(9):677-80.
7. Semin Oncol. 2009 Aug;36(4 Suppl 2):S35-45.
8. Neurology. 1979 Oct;29(10):1369-75.
9. Breast Cancer Res Treat. 2019 Jun;175(3):781-788.

2022 Independent Market Research – U.S.

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

For LM:
Diagnosis and
Therapy Selection

Total Segment:
\$160M

For PBM:
Diagnosis and
Therapy Selection

Total Segment:
\$287M

For LM:
Therapy Response,
Disease Monitoring

Total Segment:
\$255M

For PBM:
Therapy Response,
Disease Monitoring

Total Segment:
\$457M

Aggregate TAM for Diagnosis, Profiling,
and Monitoring in LM and PBM:

Total Market:
\$1.2B



CNSide

Assay Technology, Attributes, and Data



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***

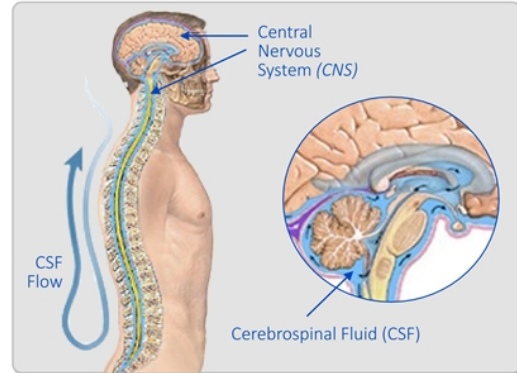
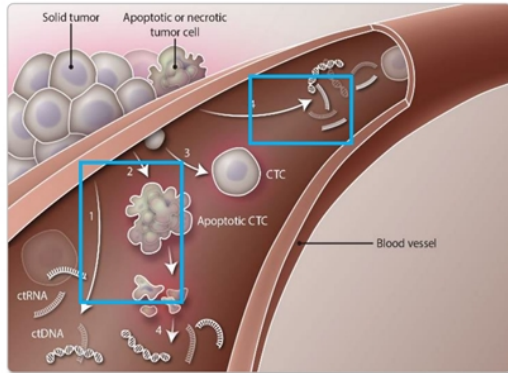
- ✓ Sensitivity: 92%
- ✓ Specificity: 100%

*(N=79 Clinical CSF Samples¹)



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

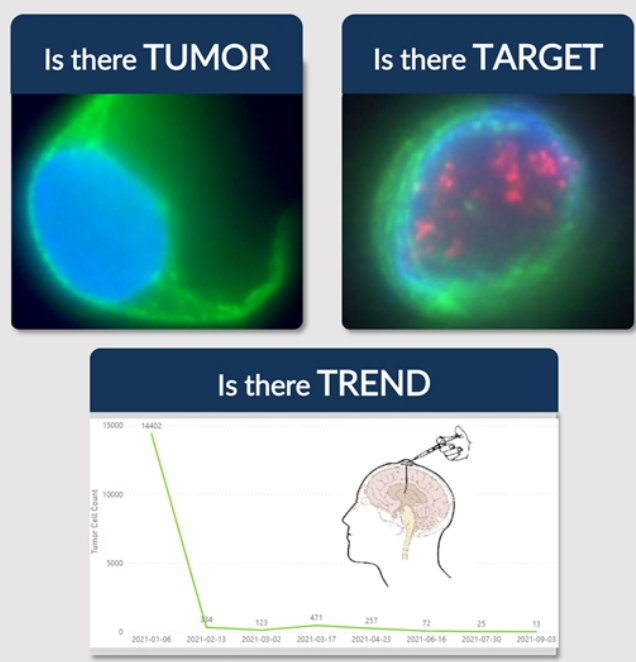


CNSide Addresses Several Unmet Clinical Needs

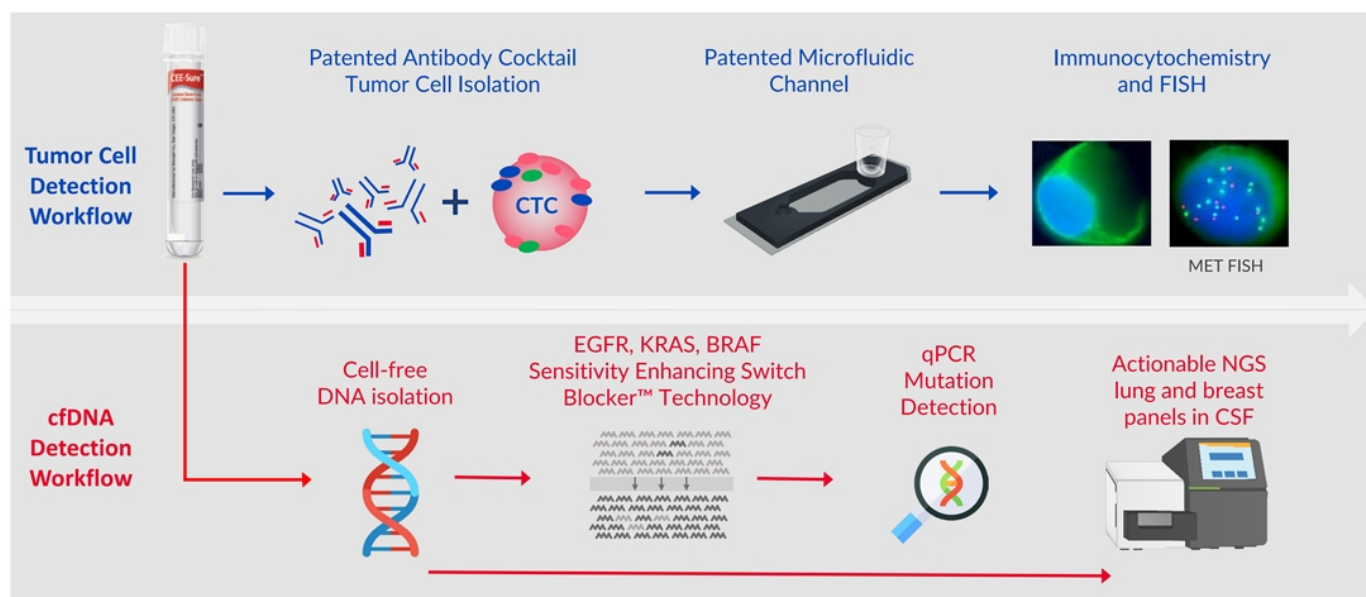
Detection of LM can be improved using cell capture technology

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

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



Biocept CNSide Proprietary Technology and Workflow*



Biocept IP Portfolio – 42 Patents Issued Worldwide

Family 1 MicroChannel for CTC Capture <ul style="list-style-type: none"> ▶ Recovery of Rare Cells using Microchannel ▶ Device for Cell Separation & Analysis 	Issued in US (3), China (3), EU PTO, Hong Kong (3), Japan, S. Korea, Canada	Expire 2025-2027
Family 2 CTC Capture With Antibody Cocktail <ul style="list-style-type: none"> ▶ Subfamily 1 – Devices & Methods of Cell Capture Analysis ▶ Subfamily 2 – Method and Reagents for Signal Amplification 	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 2030-2031
Family 3 Collection Tube <ul style="list-style-type: none"> ▶ Use of DU for Anti-Clumping of Biological Sample 	1) Issued in US	Expire 2031
Family 4 – <i>In licensed from Aegea</i> Switch-Blockers for use in real time PCR on CSF samples <ul style="list-style-type: none"> ▶ Methods for Detecting Nucleic Acid Sequence Variants 	1) Issued in US, Australia, EU PTO, Brazil, China, Hong Kong, Japan, S. Korea	Expire 2032

CNSide Publications, Posters, and Abstracts

Eight Published CNSide Documents to Date



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

Saint John's
Health Center
Providence

PACIFIC
NEUROSCIENCE
INSTITUTE™

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

Akanksha Sharma,¹ Nathan Sweeney,² Barbara Brown,² Deanna Fisher,²
Kathryn Amisley,² Steven Hsiao,² Anna Natchez,² Shiyi Hua,² Pericles Corkins,²
Tony Pachatz,² Naveed Waqar,² Jose Carrillo,² Miah Nguyen,²
Judy Tsong,² Michael Dugan,² Santosh Kumar,²
¹Department of Translational Neurosciences,
Pacific Neuroscience Institute/Providence Saint John's Cancer Institute,
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™ CNSide™ 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

Patient	Sex	Age	Primary	Treatments	OS
1	F	40	Breast (HER2+)	Taxotere, IT Methotrexate, IT Cytarabine, IT Temozolamide (Jalisco), IT Pomalidomide (Jalisco)	17 mos
2	M	70	Melanoma (PD-L1+)	IT Cytarabine, IT Thiotepa	30 mos
3	M	43	Esophageal (HER2+)	IT Thiotepa, IT Temozolamide (Jalisco)	2 mos
4	F	59	Breast (ER+, PR+)	IT Cytarabine, IT Methotrexate	7 mos
5	M	79	Neuroendocrine Carcinoma	Capecitabine, Temozolamide	5 mos

OS - Overall Survival, IT - Intrathecal

Learn more about the CNSide assay



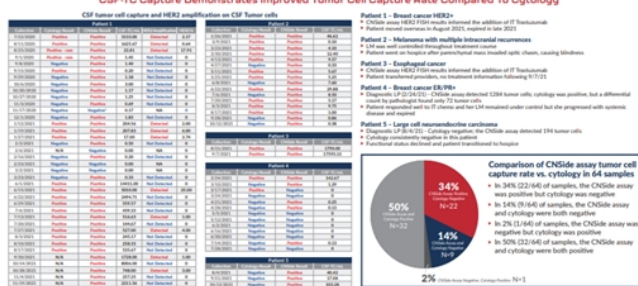
Conclusions

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



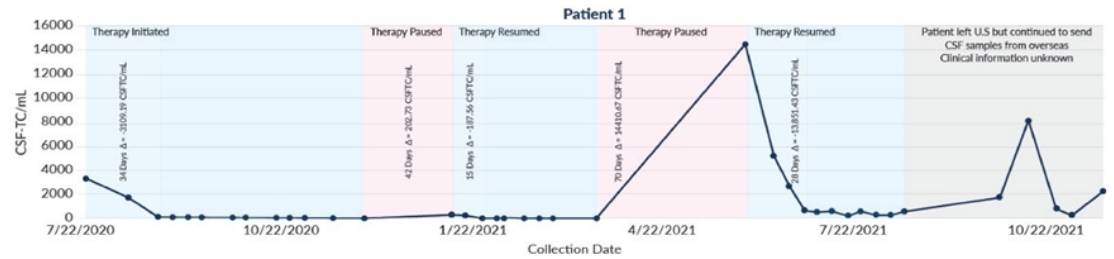
CSF-TCs Track Disease Status and Therapy Response



Case Study Demonstrating CNSide™ Utility¹

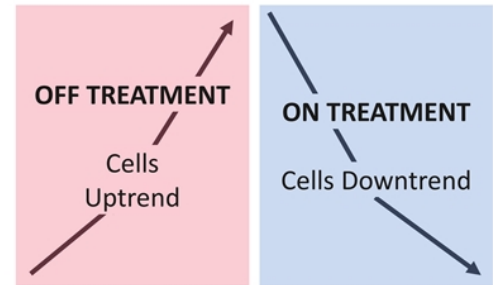
40-year-old Female

- Breast Cancer Primary Tumor
- Diagnosed with LM

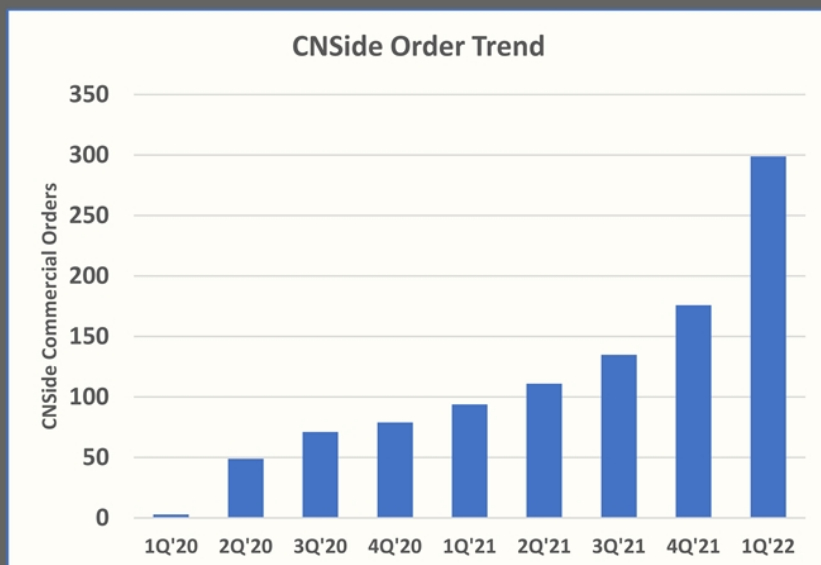


CSF tumor cell numbers detected by the CNSide assay correlated with treatment status

- ▶ 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



A blurred photograph of a hospital hallway with people walking, serving as the background for the top half of the page.

FORESEE Clinical Trial

A Prospective, Multi-Institution Study Led by Northwestern University

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

Objectives:

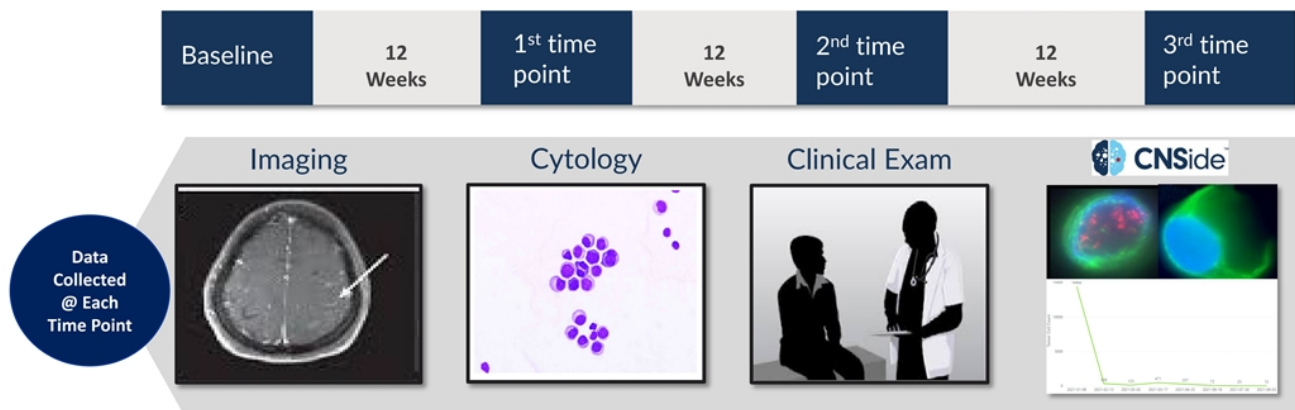
- To determine the impact of CNSide in managing Leptomeningeal Metastasis in patients with Breast or Non-Small Cell Lung Cancer
- Assess correlation of CSF Tumor cells with clinical response
- Evaluate CNSide in helping to determine course of treatment
- Study design:



Our Goal...
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

- 1 **Expand CNSide Usage Among Thought-Leaders**
 - Generate further engagement, experience, and advocacy for CNSide with this small core of experts and leaders
- 2 **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
- 3 **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
- 4 **Inclusion in NCCN Guidelines for LM**
 - Support repeat testing for therapy response monitoring
 - Expand adoption to medical oncologists

Target Market

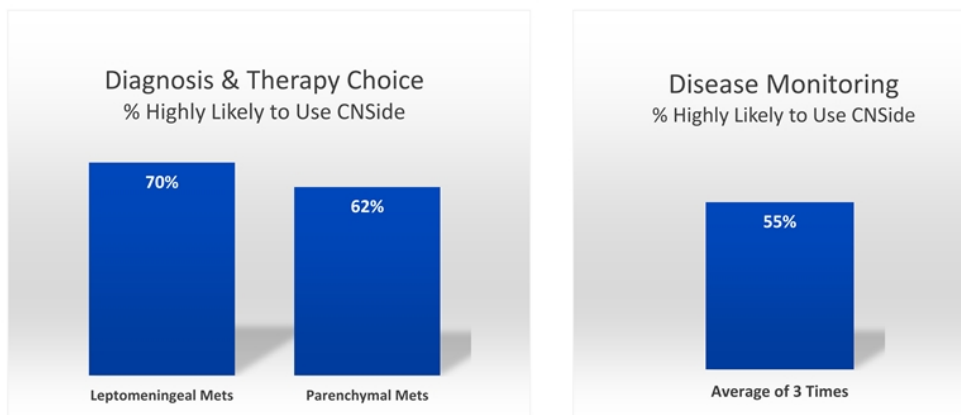
- ▶ Neuro-oncologists and thought leaders for early adoption (<1,000)
- ▶ Medical Oncologists (>12,000)

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

1 Leptomeningeal Metastasis

- Establish CSF beachhead in area with critical unmet needs
 - Significantly advance patient care and management
 - >200,000 with CNS involvement¹

2 PBM & Gliomas

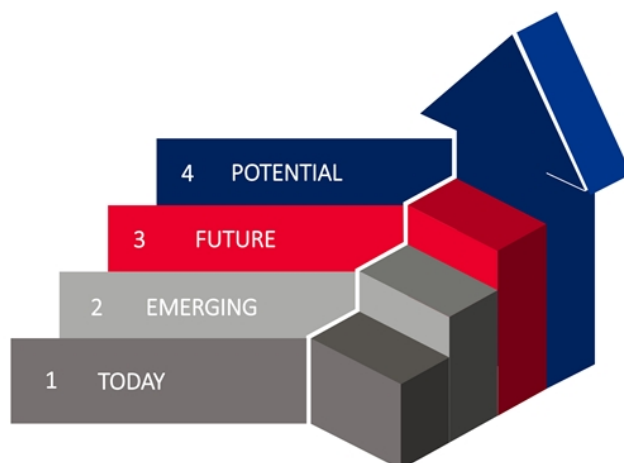
- Expand to other neuro-oncology indications
 - Parenchymal brain metastases
 - Primary brain tumors

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

4 Other neurological diseases

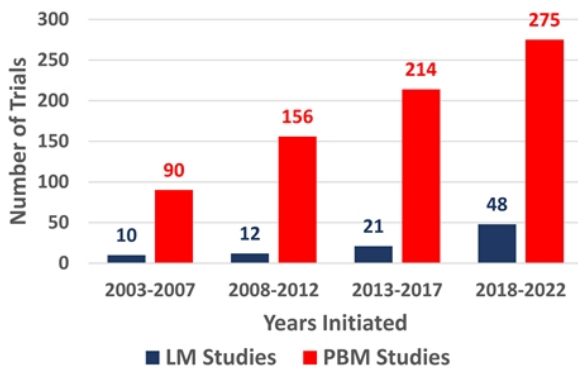
- CSF analysis as a window into other CNS disease processes²
 - Especially where cellular process are involved
 - Potential for neurodegenerative disease



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

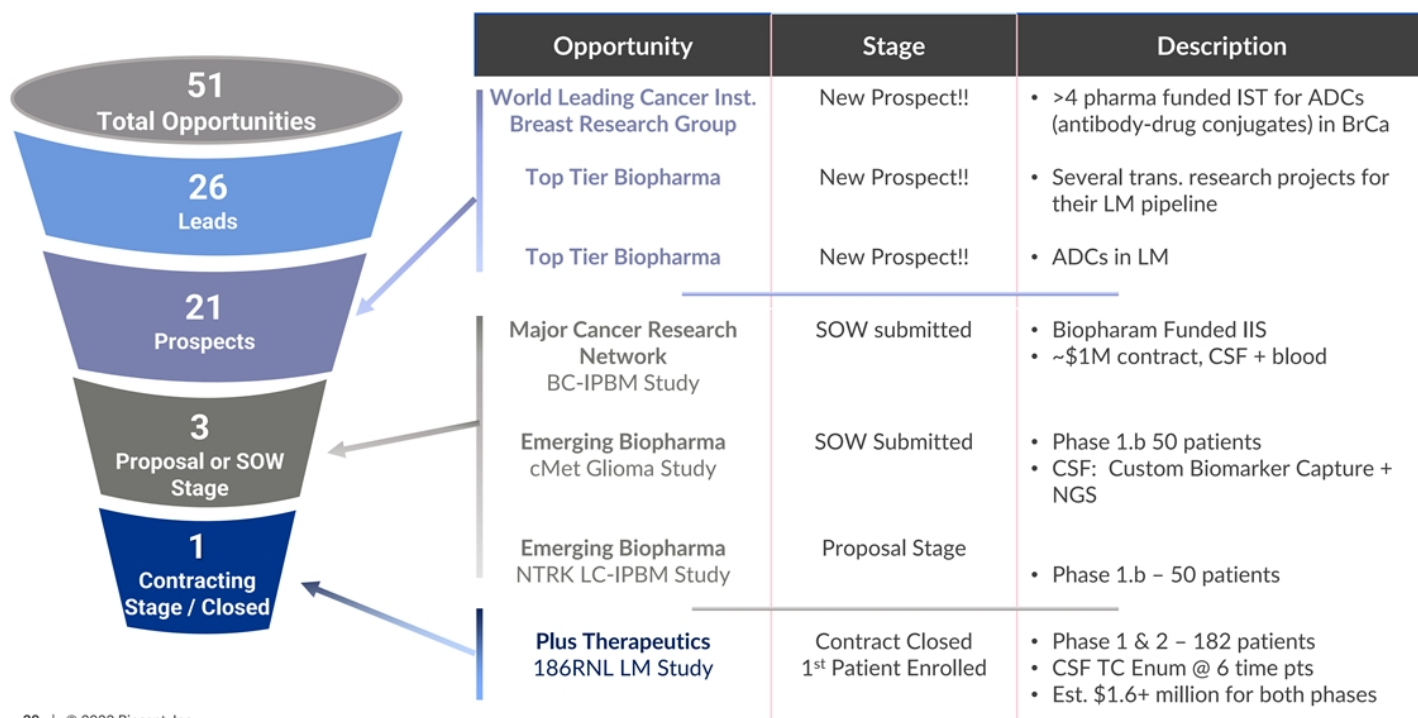
CNS Metastases Studies Initiated from 2003-2022*



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

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 higher¹
- Biopharma is investing heavily in CNS metastases therapeutic development – **100 programs initiated in past 5 years**
- 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^{2,3}
- Cancer Moonshot Initiative & ASCO recommendations⁴: 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



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
- 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

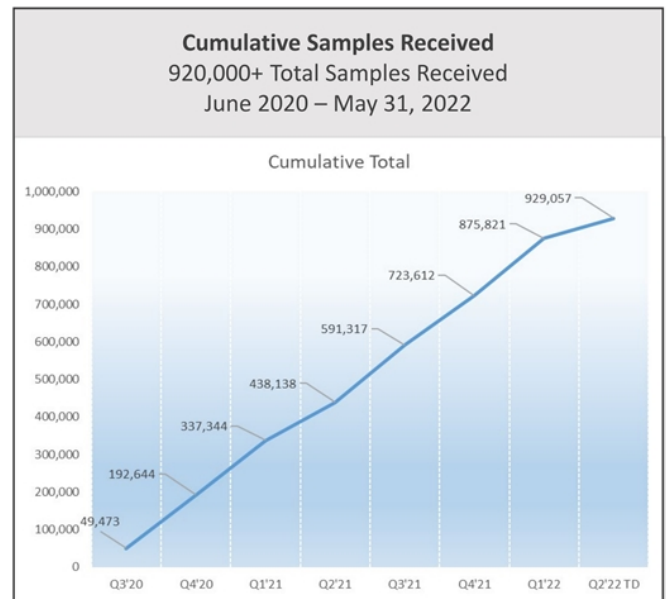
Medicare Reimbursement

- \$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

Sam Riccitelli Chair, Interim President & CEO	<ul style="list-style-type: none"> Seasoned executive with 35+ years medical device & diagnostics experience Serial oncology diagnostics entrepreneur Former COO at Genoptix, Inc.
Antonino Morales, CPA Director, Interim CFO	<ul style="list-style-type: none"> Broad leadership experience in the US and Latin America with Fortune 100 and early-stage start-up companies Senior executive/consulting roles with Citibank, Bank of America, Arthur Andersen, McDonald's, and Mazda University of Southern California; Licensed California CPA
Philippe Marchand, PhD COO	<ul style="list-style-type: none"> 20+ years experience in oncology diagnostics and biopharma industries Proven operations and technology track record as an executive Extensive experience in rare cell isolation and analysis technologies
Michael Dugan, MD CMO and Medical Director	<ul style="list-style-type: none"> 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
Darrell Taylor, JD SVP, CLO & CCO	<ul style="list-style-type: none"> 20+ years of extensive legal expertise focusing on healthcare transactional, regulatory, and compliance matters 15+ years on the provider side at LabCorp of America and other clinical and research laboratories Formerly with global law firm DLA Piper and in-house at Abbott Labs, AbbVie, and Sorrento Therapeutics The University of Texas Medical Branch and Notre Dame Law School
Michael Terry SVP, Corporate Development	<ul style="list-style-type: none"> 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 Trovagene
David Karlander SVP, Commercial Operations	<ul style="list-style-type: none"> 25+ years of industry experience including extensive oncology experience Record of success in building and managing major diagnostics brands Former executive sales and marketing positions at Exact Sciences and Novartis' Genoptix Medical Lab



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

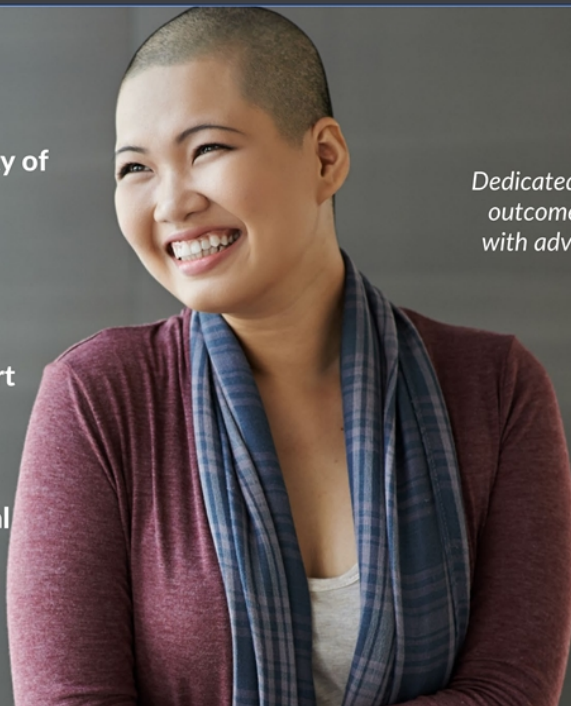
- **David Berz, MD, PhD**
Beverly Hills Cancer Center
Chief Medical Officer – Valkyrie Pharmaceuticals
Beverly Hills, California
- **Santosh Kesari, MD, PhD**
Chair, Dept. of Translational Neuro-oncology and
Neurotherapeutics, John Wayne Cancer Institute,
Santa Monica, California
- **Priya Kumthekar, MD**
Associate Professor of Neurology (Neuro Oncology)
and Medicine (Hematology and Oncology)
Northwestern Medicine
Feinberg School of Medicine
Chicago, IL

Corporate Priorities

- 1 Position Biocept as leader in emerging category of neurological tumor diagnostics
- 2 Establish CNSide as standard of care for diagnosis, identifying potential treatments and monitoring for CNS involvement
- 3 Initiate FORESEE clinical validity & utility study leading to guideline inclusion – 1st patient enrolled in 3Q'22
- 4 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 – 1st study initiated by 2022-year end
- 6 Develop additional strategic commercial and technology partnerships to accelerate neurological diagnostic offerings
- 7 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



Dedicated to improving outcomes for patients with advanced cancer.