



Biocept Issues Letter to Stockholders

January 12, 2021

SAN DIEGO--(BUSINESS WIRE)--Jan. 12, 2021-- [Biocept, Inc.](#) (Nasdaq: BIOC), a leading commercial provider of molecular testing to provide physicians with clinically actionable information to improve patient outcomes, announces that President and CEO Michael W. Nall has issued the following letter to stockholders:

To My Fellow Stockholders:

Biocept entered 2021 well-positioned to grow our core liquid biopsy oncology business while continuing to offer RT-PCR testing for the SARS-CoV-2 virus.

Oncology testing is our foundation for long-term success. We are proud to provide critical information to help physicians select the optimal treatment for their patients with cancer. Biocept is differentiated from others with liquid biopsy platforms in that our Target Selector™ leverages information from both circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA) in blood and, more recently, in cerebrospinal fluid (CSF). This is very important as there is information gained from each of these targets that is critical for optimal patient care.

Among key initiatives for the coming year is to advance our Target Selector™ CSF assays toward standard of care for diagnosing and monitoring central nervous system metastases. This unique offering afforded by our proprietary rare cell capture technology platform presents an opportunity to serve a sizable market with more than 100,000 patients per year diagnosed with metastatic tumors to the brain in the U.S., as well as a competitive advantage for Biocept within our industry.

Biocept also is working hard to support the fight against COVID-19. Since making the decision to broaden our offering and initiate this testing service in June 2020, we have received more than 200,000 samples. Our team has processed these tests quickly, with the vast majority of results sent to health providers within 48 hours of sample receipt. Due primarily to our COVID-19 testing services, our revenues through the first nine months of last year surpassed our full-year revenues for all prior years. We expect COVID-19 testing will continue to be a meaningful component of our business this year, contributing to revenues and improving cash flow throughout 2021 or until the pandemic subsides.

Focus on Neuro-Oncology

Last year we launched our Target Selector™ CSF assays for diagnosing and monitoring lung and breast cancer that has metastasized to the brain and central nervous system. Depending on the type of cancer, between 10% and 30% of adults with cancer will develop brain metastases. Detecting metastases in CSF is critical as advances in treatment strategies and new targeted therapies are helping patients with this type of metastatic cancer to live significantly longer.

Our new assays fill a significant market need as the current standard of care, CSF cytology, has very limited sensitivity to detect metastases and provides no information about molecular targets for therapy choice. Further, CSF cytology frequently results in negative results when tumor involvement of the central nervous system is suspected, which often leads to repeat attempts to collect CSF samples from lumbar punctures. Our initial studies show that Target Selector™ allows for a more sensitive, cell-specific and quantitative assessment of tumors in CSF, allowing for the diagnosis of metastases and providing information about molecular alterations that can aid in the choice of therapy.

We are beginning to gain recognition within the medical community as our study results were featured at several major international scientific meetings last year. Additional initiatives underway to support physician adoption include working with key opinion leaders as study collaborators to further establish the clinical utility of our Target Selector™ CSF assays and advance our assays toward standard of care. While CSF assays currently represent a small percentage of our business, we expect volumes to continue to increase each quarter as we progress through 2021.

This groundbreaking work in CSF and overall advancements with our oncology business are being led by Michael Dugan, MD, who joined Biocept in mid-August as our Chief Medical Officer and Medical Director. Dr. Dugan is highly regarded in the pathology and molecular diagnostics industry and has served in leading medical positions at several high-profile diagnostics firms. We are pleased to have him on the Biocept team.

Update on Oncology Testing Business

Like other molecular biology companies, our oncology testing business has been impacted by the pandemic. We fully expect test volumes will return to historical levels as the pandemic subsides. In the meantime, our strategy is to take actions that position us for a strong future. Among these is entering into new provider agreements with integrated health systems and other capitated plans that provide quality healthcare delivered cost-effectively. By using a liquid biopsy with blood or CSF, our oncology assays are a cost-efficient means to profile for biomarkers that impact therapy and to monitor disease progression over time.

As a notable win last year, we signed an agreement for all Target Selector™ assays with Highmark Health, the nation's second-largest integrated health delivery network and a Blue Cross Blue Shield affiliate. The agreement followed a rigorous two-year evaluation under Highmark's Vitals program that showed our assays helped physicians rapidly assess the molecular status of patients with advanced non-small cell lung cancer and select the most appropriate therapy, while reducing the overall cost of care.

Update on COVID-19 Testing Initiatives

To date we have been purchasing the components for COVID-19 collection kits from third parties, assembling the kits in-house and distributing them to customers. Last year we announced our intention to develop our own COVID-19 specimen collection media. We have received independent validation that the Biocept-developed media inactivates the virus in transport tubes. As many investors understand, supply chain challenges are widespread for equipment and materials required for products related to COVID-19 testing, and the equipment needed to produce our collection tubes has been delayed due to backorders from the manufacturer. We recently received the backordered equipment needed to complete our own COVID-19 collection kits. We will be installing, calibrating and validating the equipment in the coming weeks.

We are now in the process of completing the final validation and testing phase of the COVID-19 assay development project with Aegea Biotechnologies and we expect the assay to be ready for deployment in clinical testing laboratories in the first quarter of 2021. The Aegea COVID-19 assay will utilize the patented Switch-Blocker technology. This COVID-19 assay incorporates several unique features that could potentially aid caregivers in their clinical decision. Those capabilities include the ability to determine which COVID-19 strain is present, which may be important in determining therapeutic strategy. Also the assay is quantitative so physicians can measure the viral load, which can potentially be used to monitor disease progression. When development is complete, Biocept has a first option to negotiate expansion of our COVID-19 testing capabilities with this next-generation offering.

Corporate Priorities

Beyond our COVID-19 initiatives, corporate priorities for our core oncology business in 2021 are as follows:

- Increasing market penetration of Target Selector™ assays with a focus on neuro-oncology, in addition to urology, breast and lung cancer;
- Entering into additional studies with respected institutions to further prove the clinical utility of our offerings;
- Publishing clinical case studies and presenting data at scientific conferences that further validate our Target Selector™ testing;
- Growing sales of our Target Selector™ molecular assay research-use only (RUO) kits and our CEE-Sure blood collection tubes;
- Receiving payment from Medicare for our Target Selector™ NGS assay developed under our collaboration with Thermo Fisher;
- Entering into additional strategic commercial and technology partnerships, both global and domestic;
- Signing additional agreements with third-party health plans including capitated plans, and expanding our relationship within the Blue Cross Blue Shield network;
- Launching additional assays both in blood and CSF; and
- Strengthening our patent portfolio in the U.S and internationally.

To support our many priorities, we are fortunate to have resources aligned to pursue these markets. In addition, we recently relocated to a new facility in San Diego that meets our corporate needs and is expected to reduce rent and other facility costs by approximately 15-20% annually.

I am so very proud of our hard-working team at Biocept. They have rallied to support public health needs with our COVID-19 testing, while continuing to provide excellent service for our core oncology clients and the patients under their care. Indeed, it is our commitment to superior customer service that is being so warmly embraced by our customers. As always, all of us at Biocept are committed to improving patient treatment choices and clinical outcomes.

Sincerely,

Michael W. Nall
President and Chief Executive Officer
January 12, 2021

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. The Company's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (ctDNA). With thousands of tests performed, the platform has demonstrated the ability to identify cancer mutations and alterations to inform physicians about a patient's disease and therapeutic options. Additionally, Biocept is offering nationwide COVID-19 polymerase chain reaction (PCR) testing to support public health efforts during this unprecedented pandemic. For additional information, please visit www.biocept.com.

Forward-Looking Statements Disclaimer Statement

This release contains forward-looking statements that are based upon current expectations or beliefs, as well as a number of assumptions about future events. Although we believe that the expectations reflected in the forward-looking statements and the assumptions upon which they are based are reasonable, we can give no assurance that such expectations and assumptions will prove to have been correct. Forward-looking statements are generally identifiable by the use of words like "may," "will," "should," "could," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. To the extent that statements in this release are not strictly historical, including without limitation statements regarding the ability of our assays to provide physicians with clinically actionable information to improve patient outcomes, our ability to advance our Target Selector™ CSF assays toward standard of care for diagnosing and monitoring central nervous system metastases, anticipated revenues for full year 2020, our expectations regarding COVID-19 testing as a component of our business during 2021, our expectations regarding volumes of CSF assays during 2021, our expectations regarding oncology test volumes returning to historical levels as the pandemic subsides, the timing of availability of Biocept developed COVID-19 specimen collection kits, timing for completion of the final

validation and testing phase of the COVID-19 assay development project with Aegea Biotechnologies and availability of the same, whether Biocept will be able to expand its COVID-19 testing capabilities by adding the Aegea Biotechnologies COVID-19 assay, our ability to increase market penetration and increase sales, our ability to enter into additional studies and publish clinical case studies, our ability to receive payments from Medicare, our ability to enter into additional strategic commercial and technology partnerships and additional agreements with third-party health plans, our ability to expand our relationship within the Blue Cross Blue Shield network, our ability to launch additional assays, and our ability to strengthen our patent portfolio, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous risks and uncertainties, including the risk that our products and services may not perform as expected and the risk that we will not be able to enter into additional services agreements. These and other risks are described in greater detail under the "Risk Factors" heading of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. The effects of such risks and uncertainties could cause actual results to differ materially from the forward-looking statements contained in this release. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law. Readers are advised to review our filings with the SEC, which can be accessed over the Internet at the SEC's website located at www.sec.gov.

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