

March 1, 2016

# **Biocept Issues Letter to Stockholders**

# Revenue-producing sample volume during 2015 increases by more than 30% each consecutive quarter to greater than 1,800 for the year

SAN DIEGO, March 1, 2016 /PRNewswire/ -- Biocept, Inc. (NASDAQ: BIOC), a molecular diagnostics company commercializing and developing blood-based biomarkers to improve the detection and treatment of cancer, announces that President and CEO Michael W. Nall has issued the following letter to stockholders:

To Our Stockholders and Friends:

This year is off to a solid start and we anticipate it to be highly productive as we build on our position as a commercial leader in the fast-developing field of liquid biopsy. Key to success in this emerging industry is test adoption by the medical community, and I'm proud to report that our revenue-producing sample volume exceeded 1,800 for 2015 with each quarter showing sequential growth of more than 30%.

I'm excited to share some of the initiatives we have planned for 2016 as we seek to grow our customer base and advance our business strategy with the goal of driving test volume. These include:

- expanding our test menu with new biomarkers, including the anticipated introduction of a test with direct relevance to many of the new cancer immunotherapies in clinical development;
- initiating new clinical validation and utility studies, many of which we believe will be in collaboration with wellrecognized, leading oncology institutions;
- establishing a Clinical Advisory Board with key opinion leaders to guide us in expanding our physician customer base;
- developing additional contracts with health plans to support reimbursement of our tests; and
- partnering with pharmaceutical companies to assist them in developing therapies, which could provide us with future opportunities to develop assays, or companion diagnostics, that help qualify patients for emerging targeted therapies in early-stage clinical trials.

We look forward to providing some detail around our initiatives during our year-end investment community conference call on March 9 and subsequently reporting on our progress throughout the year.

The field of liquid biopsy is a multifaceted one and many of you have asked about where Biocept fits. We focus on two segments: the *profiling* and the *monitoring* of specific biomarkers in the blood of patients who have been diagnosed with cancer. We currently have commercialized assays based on our patented and proprietary technology for lung, breast, gastric and colorectal cancers, melanoma and, most recently, prostate cancer - all of which have been validated by our onsite CLIA-certified, CAP-accredited laboratory. Our tests provide physicians with important information in making treatment decisions at the time of diagnosis, at disease recurrence and during treatment. These are significant markets with one industry report projecting worldwide sales from liquid biopsy profiling at \$7 billion and monitoring at \$5 billion by 2020.\*

An obstacle to developing liquid biopsy tests for cancer is achieving sufficient sensitivity to detect very small amounts of tumor material in bodily fluids. We chose to base our tests on blood because a higher concentration of tumor cells and cancer DNA fragments are found in blood for most solid tumor cancers compared with other fluids, including urine. I'm delighted to report that our tests are showing high specificity (i.e., true negative readings) and sensitivities (i.e., true positive readings) with strong correlations with tissue biopsies. In fact, we recently demonstrated a 93% correlation with tissue biopsies in patients with lung cancer, with that data presented both at the Association for Molecular Pathology meeting in November and just last week at the UCSD Moores Cancer Center Translational Oncology Symposium.

We also believe that no single approach can produce the best results for a variety of biomarkers. To that end, we offer several methods of detecting tumor cells through our highly versatile, patented platform utilizing both circulating tumor cells (CTCs) from blood and circulating tumor DNA (ctDNA) from plasma.

Importantly, the number of physicians using our tests is increasing. Physicians make decisions and change behavior based on scientific evidence. The uptake in our test volume reflects our ability to accumulate clinical evidence from collaborations with highly reputable institutions that validate our approach.

The past year has not been without its challenges. Notable among these has been revenue collection for tests we have performed. We attribute our collection difficulties mainly to new and changed medical billing codes that caused confusion among payers, as well as our need to improve billing processes and procedures. We have been highly focused on resolving these issues and we believe that we are making good progress that we expect will improve timely collections and generate more revenues per test. We also are developing relationships with medical plans to support reimbursement. As a result, the number of patients with access to our liquid biopsy assays through their healthcare insurance plans has now reached approximately 140 million.

We are excited to build on our momentum in 2015 and to deliver on the value-creating goals planned for this year. On behalf of my colleagues, our Board and our advisors, thank you for your continued support of Biocept.

Sincerely,

Michael W. Nall

President and Chief Executive Officer

## A Review of our 2015 and Recent Accomplishments

#### Commercial Biomarker Launches

- Expanded our non-small cell lung cancer (NSCLC) diagnostic capabilities to include biomarkers for EGFR and ROS1 mutations.
- Launched assays for KRAS and BRAF mutations, expanding into colorectal cancer and melanoma, respectively, and increasing the detection for other solid tumors.
- Expanded our assay menu with FGFR1 amplification, which has been identified in breast cancer and in both small cell lung cancer and NSCLC.
- Launched the c-MET amplification detection test, which assists in identifying patients who may be receptive to certain gastric and NSCLC treatments.

#### Collaborations

- Advanced our collaboration with Rosetta Genomics to proof-of-concept studies aimed at utilizing microRNAs to enhance lung cancer diagnosis, following the successful completion of our feasibility studies.
- Announced collaboration with Baylor College of Medicine to develop molecular diagnostic assay platforms to detect mutations in ESR1.
- Partnered with the University of California, Irvine to evaluate biomarkers detected from blood -based versus tissue biopsies in metastatic cancers.
- Entered into collaboration with the Sarah Cannon Research Institute, the global cancer enterprise of Hospital Corporation of America, for the detection of estrogen positive (ER+) breast cancer.
- Announced a collaboration with the University of California San Diego Moores (UCSD) Cancer Center to demonstrate the clinical utility of our biomarker in NSCLC.
- Announced collaboration with Insight Genetics to develop an enhanced diagnostic for the ALK mutation, a major therapeutic target in the treatment of NSCLC, which resulted in a poster presentation at the American Society of Clinical Oncology Annual Meeting.

#### Industry Conferences and Study Results

- Reported results of a prospective study at Columbia University demonstrating a high concordance of our blood-based versus tissue biopsy results in patients with primary and metastatic breast cancer. This was published in Clinical and Translational Oncology in February 2015.
- Announced presentations of data from research with Biocept assays at SelectBIO Biofluid Biopsies & High-Value Diagnostics 2015 Meeting, Association for Molecular Pathology Annual Meeting, International Association for the Study of Lung Cancer's Annual World Conference on Lung Cancer, Next Generation Dx Summit, American Society of Clinical Oncology Annual Meeting and UCSD Moores Cancer Center Translational Oncology Symposium.

#### Healthcare Payer Agreements

Entered into agreements with Blue Cross Blue Shield of Illinois, MultiPlan Inc., Fortified Provider Network, Three Rivers Provider Network, Stratose, Galaxy Health Network and America's Choice Provider Network to provide innetwork coverage for our tests.

#### Patents

Announced multiple patent awards for our microchannel and cell capture technologies, both in the U.S. and overseas.

#### Corporate

- Expanded our molecular diagnostic development expertise with the appointment of Jason Poole, Ph.D. as Senior Director, Molecular Assay Development.
- Announced the additions to our Scientific Advisory Board of Marileila Varella Garcia, Ph.D., from the University of Colorado at Denver, an expert in the molecular and cytogenetic analysis of cancer, and David Rimm, M.D., Ph.D., from Yale University School of Medicine, a noted physician and researcher in the area of clinically actionable oncology biomarkers.

Biocept also completed an offering of stock and warrants in February 2015 that to date has raised more than \$18 million. In December 2015 Biocept entered into a \$15 million common stock purchase agreement with Aspire Capital Fund, LLC (Aspire), with Aspire purchasing the first \$1 million at a premium to that day's closing price.

\*J.P. Morgan Industry Report, May 27, 2015

# **About Biocept**

Biocept, Inc. is a commercial-stage molecular diagnostics company that utilizes a proprietary technology platform and a standard blood sample to provide physicians with important prognostic and predictive information to enhance individual treatment of patients with cancer. Biocept's patented technology platform captures and analyzes circulating tumor DNA, both in CTCs and in plasma (ctDNA). Biocept currently offers assays for gastric cancer, breast cancer, lung cancer, colorectal cancer, prostate cancer and melanoma, and plans to introduce additional CLIA-validated tests for other solid tumors in the near term. For additional information, please visit <u>www.biocept.com</u>.

## 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 as to the potential of our diagnostic assays to improve the detection and treatment of cancer, our ability to build on our position as a commercial leader in the field of liquid biopsy, our ability to accomplish our planned initiatives for 2016 and the ability of such initiatives to grow our customer base and advance our business strategy, the market size of our liquid biopsy technology, our ability to improve our collections and generate more revenues per test, and our ability to introduce CLIA-validated tests in the future, 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 risk factors as set forth in our Securities and Exchange Commission (SEC) filings. 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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