

Biocept

Completing the Answer™

Biocept Issues Letter to Stockholders

February 20, 2019

Focus on new market segments and strategies to drive growth

SAN DIEGO, Feb. 20, 2019 /PRNewswire/ -- [Biocept, Inc.](#) (NASDAQ: BIOC), a leading commercial provider of liquid biopsy tests designed to provide physicians with clinically actionable information to improve the outcomes of patients diagnosed with cancer, announces that President and CEO Michael W. Nall has issued the following letter to stockholders:



To Our Stockholders:

We are excited about 2019, as we pursue a strategy that we believe will achieve long-term success by:

- Increasing physician adoption of our liquid biopsy testing in Medical Oncology by emphasizing cancer monitoring for progression and/or response to cancer therapeutics;
- Broadening the use of our testing and technology by entering new markets such as urology, pathology and integrative oncology;
- Expanding our global footprint with our distributed kit and liquid biopsy specimen collection tube products; and
- Growing volume and revenue while containing costs.

At Biocept, we are proud of our position as a pioneer in the liquid biopsy diagnostics market and are pleased to see that clinical diagnostics are being recognized for their role in improving patient care and reducing healthcare costs. As more precision medicine-driven therapies are commercialized, the need for biomarker information becomes even more important. Physicians are increasingly aware of the shortcomings of profiling cancer biomarkers using only invasive and expensive tissue biopsies, which often yield insufficient or untimely results.

Our Target Selector™ tests require a simple blood sample and allow for profiling cancer biomarkers in a way that is non-invasive, rapid and cost-effective. Among liquid biopsy companies Biocept stands apart by offering a patented methodology through our Target Selector™ platform that can isolate cancer material from circulating tumor cells (CTCs) or from cell-free circulating tumor DNA (ctDNA). From this platform, we have developed a robust menu of highly sensitive and specific tests to identify cancer biomarkers and provide physicians with actionable information.

Late last year we revamped our commercial organization by recruiting diagnostics industry veteran Edwin Hendrick, who joined us in late September as Chief Commercial Officer. His team of professionals have proven success in diagnostic sales, marketing and health plan reimbursement. They are implementing a comprehensive strategy that includes contracting with major cancer treatment institutions, increasing patient access to our testing platform, and rolling out new tests and service offerings.

We have taken a fresh look at assessing the advantages of our liquid biopsy testing and are developing new approaches to further engage current customers while also expanding into additional oncology segments. A compelling attribute of our Target Selector™ testing is the use of CTCs as well as ctDNA which extends our testing beyond profiling at diagnosis to include monitoring for both response to therapy and for potential disease progression. Offering both CTC and ctDNA testing differentiates Biocept from the other major commercial liquid biopsy companies. Our commercial team has identified patient monitoring as an area of high unmet need in urology, breast cancer and in integrative oncology, a practice that combines complementary modalities and a whole-body approach in conventional cancer care planning.

We have also relaunched our EmpowerTC™ Pathology Partnership service. This initiative is designed to expand access to our Target Selector™ testing by involving pathologists around the country in the interpretation of liquid biopsy testing. This is another differentiator of Biocept in the marketplace and is anticipated to benefit from the trend of community physicians and hospitals seeking to partner with leading-edge medical solutions to improve patient care and to improve economics within their local health systems. We believe that these new and relaunched strategies are all gaining traction.

As most of you know, collaborating with respected institutions to produce real-world validation for the high sensitivity of our tests is critical to physician adoption. Last August, we entered into a collaboration with Highmark Blue Cross and its subsidiary Allegheny Health, a large integrated healthcare delivery system in Pennsylvania. This collaboration is evaluating the clinical utility of our Target Selector™ testing, as well as the economic value of our liquid biopsy solution for both profiling and monitoring actionable biomarkers in patients with advanced lung cancer.

According to Allegheny Health, between 2011 and 2013 fewer than 60% of patients with lung cancer at large tertiary care hospitals were tested for molecular biomarkers such as *EGFR*, *ALK* or *ROS1*, and physicians lacked information that was important to developing individualized treatment plans. Oncologists in the Allegheny Health network have now begun adopting our tests, and we are pleased to report that we have accrued approximately 24% of the patients planned for the study initiative under the collaboration. Data collected so far has shown the identification of actionable biomarkers in multiple patients tested.

In another initiative to increase real-world validation for Target Selector™ testing, we are documenting individual case reports in peer-reviewed journals. The most recent series was published in the January 2019 edition of the peer-reviewed journal, *Clinics in Oncology*. These three case reports underscore the clinical utility of our ctDNA testing in managing patients with advanced non-small cell lung cancer, or NSCLC, by detecting *EGFR* mutations, which are among the most frequently evaluated biomarkers for lung cancer. The results of our testing were used by a medical oncologist when tissue samples were inadequate to direct targeted *EGFR*-directed therapy in patients being treated for NSCLC. The case studies demonstrated that one patient had a complete response due to the anti-*EGFR* treatment, while the therapy of the other two patients was changed based on Target Selector™ results to include a third-generation tyrosine kinase inhibitor after their lung cancer had progressed and a resistance mutation was identified in their blood. Identifying these resistance mechanisms can be crucial for optimal patient management and relying on tissue biopsy alone is often not practical.

To expand our technology platform and market reach, in 2018 we entered into a broad agreement with Thermo Fisher Scientific. This collaboration gives us access to Thermo Fisher's next-generation sequencing, or NGS, products and supports our plan to commercialize a molecular oncology assay panel. Our initial priority is validating Thermo Fisher's OncoPrint™ NGS Panel in our CLIA-certified laboratory, and final panel optimization is currently underway. Once validated, this partnership will enable us to team up with Thermo Fisher to market molecular diagnostic products and services to pharmaceutical companies. Further, Biocept will be the only liquid biopsy company offering individual cancer biomarker tests with the option of a larger test panel. The agreement also calls for Biocept to become a Thermo Fisher Liquid Biopsy Center of Excellence.

In addition to these and other domestic initiatives, we plan to broaden our international footprint and establish Biocept as a global brand by distributing our products for use in laboratories internationally. We recently announced the launch of our liquid biopsy kits, marking an important step in our global brand strategy and advancing the transition of Biocept from a reference laboratory only to a comprehensive diagnostics provider. We are leveraging our strong patent position to market Research Use Only (RUO) kits to enable laboratories internationally to leverage our Target Selector™ assay technology for cutting-edge liquid biopsy testing. We are particularly excited about this endeavor as, according to a recent industry report, the use of liquid biopsy testing is growing faster in several markets outside the U.S.¹ In February 2019 we reported that we had signed our first international agreement with a leading provider of genomics sample and bioinformatics services, Agiomix FZ-LLC.

Another aspect of this strategy is making our patented CEE-Sure® blood collection tubes for Research Use Only (RUO) available through VWR, a leading global provider of products and services to laboratory and production customers. Our proprietary collection tubes provide the advantage of safe transport of patient specimens used in liquid biopsy testing without specimen degradation.

We are proud to have tested more than 17,000 patient samples and performed more than 60,000 total Target Selector™ tests, which provides us with a significant database of information. In December 2018 we entered into an agreement with Prognos, Inc. to further develop this database asset. Prognos is an innovator in predicting disease by applying artificial intelligence to clinical laboratory diagnostics and focuses on using information to drive decisions earlier in collaboration with payers, life science, and diagnostics companies. The Prognos Registry is the largest source of clinical diagnostics information in 50 disease areas, containing over 20 billion medical records for some 185 million patients.

We also have a growing IP portfolio, and now have 31 issued patents worldwide in 16 countries. We plan to continue to expand and vigorously enforce our IP in our market space.

Internally, we have focused on automation in our CLIA laboratory to improve workflows and reduce costs. We have hired new leaders in quality, regulatory and laboratory operations with the goal of building a business that can be scaled more efficiently. We also took actions last year to reduce certain expenses and we retired our long-term debt, eliminating more than \$2 million in annual cash spend to service the prior debt. This allows more resources to be focused on growing our business.

As we move through 2019, we are focused on the following initiatives:

- Increasing the market penetration for our Target Selector™ testing;
- Entering into strategic commercial and technology partnerships in the U.S. and in international markets;
- Completing validation of the Oncomine™NGS Panel;
- Implementing our diagnostic kit launch strategy and growing distribution of our blood collection tubes internationally;
- Launching our Artificial Intelligence initiative with Prognos to evaluate monetizing de-identified information from our liquid biopsy testing platform;
- Signing new third-party health plan agreements;
- Publishing more clinical case studies;
- Commercializing additional oncology biomarker assays; and
- Continuing to pursue patents on our proprietary platforms.

In summary, we are pursuing multiple avenues to capitalize on our proprietary Target Selector™ platform to drive adoption, grow revenues, and create stockholder value. As always, our primary focus is to provide physicians with the necessary information to select the best treatment pathways and to improve outcomes for patients with cancer.

Sincerely,

Michael W. Nail
President and Chief Executive Officer

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 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 plasma (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. 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 as to our ability to improve the outcomes of patients diagnosed with cancer, our ability to achieve our goals and initiatives outlined in our 2019 strategy, our ability to broaden the use of our proprietary technology platform, the success of our Pathology Partnership initiative, the success of our collaboration with Thermo Fisher Scientific, our ability to grow our domestic and international footprint, our ability to become a comprehensive diagnostics provider, our ability to expand and enforce our IP portfolio, our ability to scale our business efficiently, and our ability to drive adoption, grow revenues and create stockholder value, 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 <https://www.sec.gov>.

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¹Liquid Biopsy Market Size, Share & Trends Analysis Report By Application, By Sample Type (Blood, Urine) By Biomarker Type (CTC, ctDNA, Exosomes), By Technology (NGS, PCR), By Region, And Segment Forecasts, 2018 - 2030

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