Biocept Reports 2019 Fourth Quarter and Full Year Financial Results

March 25, 2020

- Fourth quarter revenues reached a record $1.8 million, up 108% over the fourth quarter of 2018 and up 17% over the third quarter of 2019
- Fourth quarter commercial revenues increased 94% over the fourth quarter of 2018 and increased 11% over the third quarter of 2019
- Fourth quarter cost of revenues per accession declined 12% versus the fourth quarter of 2018
- Full year 2019 revenues increased 70% and the number of commercial samples received increased 35% over full year 2018
Conference call begins at 4:30 p.m. Eastern time today

SAN DIEGO, March 25, 2020 /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 cancer patients, reports financial results for the three and 12 months ended December 31, 2019, and provides an update on its business progress.

"I'm pleased to report our sixth consecutive quarter of growth with fourth quarter revenues reaching a record $1.8 million, more than double the prior year's quarterly revenues," said Michael Nall, President and CEO of Biocept. "Our growth for the quarter was driven by year-over-year increases of 46% in commercial test volume and 34% in average reimbursement per patient, predominantly due to reporting on more tests per accession ordered by referring doctors. While growing revenues, we also benefitted from operating efficiencies, including automation initiatives in our CLIA-certified laboratory. These efficiencies combined with higher sample volume moved us significantly closer to positive gross margin. We have more actions to complete the automation of our lab and we are pleased with the contribution from these efforts so far.

"Revenue for the full year 2019 increased 70% over the prior year," said Mr. Nall. "A key growth driver throughout 2019 was our decision to focus on prostate cancer, including committing more commercial resources to urologists and urology practices and introducing additional prognostic and predictive biomarker tests. As the year progressed, we were encouraged that more urologists were using more biomarkers per test for more of their patients.

"I'm exceptionally proud of our strong operational performance throughout 2019 and into 2020. Among notable accomplishments, we launched the first-and-only liquid biopsy test to evaluate cerebrospinal fluid as well as NGS test panels for lung and breast cancer. We also added a new revenue stream from sales of our Target Selector™ research-use only (RUO) kits, further expanded our intellectual property portfolio with newU.S. and foreign patents, and presented compelling data further validating our technology at multiple scientific conferences and in peer-reviewed journals," he added. "So far this year, we have raised net proceeds of $17.5 million from two equity offerings and warrant exercises, positioning us for continued execution on our growth strategy."

2019 and Recent Highlights

Commercial Launches

- Announced the availability of Target Selector™ assays to evaluate cerebrospinal fluid (CSF) for the presence of circulating tumor cells (CTCs) and biomarkers, which may be indicators of brain metastases. Of patients diagnosed with breast and lung cancer, 30% and 36%, respectively, will develop brain metastases. The validations study for the CSF assay was conducted in collaboration with Providence St. Joseph Health, Southern California, and its wholly owned affiliates Providence St. John's Health Center and John Wayne Cancer Institute.
- Launched Target Selector™NGS Lung Panel and Target Selector™NGS Breast Panel, the Company's first two multi-gene liquid biopsy panels, differentiating Biocept as the only commercial liquid biopsy provider of single-biomarker testing, tumor-specific panels and CTC analysis. The NGS Panels run on Thermo Fisher Scientific's Ion Torrent™ NGS platform and are being marketed to physicians and researchers for the detection and monitoring of actionable biomarkers associated with these tumor-specific cancers.
- Launched Target Selector™ pan-TRK assay for the detection of TRK proteins, which are actionable biomarkers that can be used to qualify patients for treatment with TRK inhibitor therapies. The pan-TRK assay, which utilizes Biocept's proprietary CTC platform to screen for TRK gene alternations, is a unique liquid biopsy offering.
- Launched expanded pathology partnership service, EmpowerTC™, with additional prognostic and predictive biomarker tests to enable urology and uropathology practices to perform liquid biopsy testing and interpret results generated in Biocept's CLIA-certified laboratory.
- Announced the availability of RUO kits, which enable molecular laboratories around the world to utilize Target Selector™ circulating tumor DNA (ctDNA) assays to perform liquid biopsy testing. Also announced an agreement with Agiomix FZ-LLC, a provider of genomics sample and bioinformatics services for research and clinical applications, to validate and purchase Biocept's Target Selector™ RUO kits for use in its laboratory.

Commercial Agreements

- Announced an agreement with Beacon Laboratory Benefit Solutions designating Biocept as a BeaconLBS® Lab-of-Choice, increasing patient access to Biocept' liquid biopsy testing platforms. Beacon Laboratory is a nationally recognized provider of laboratory benefit management technology solutions to U.S.-based health and managed care companies.
- Signed an agreement with a large California-based independent physician association (IPA) to provide Biocept's Target Selector™ liquid biopsy testing services to physicians and patients in their network.

Regulatory Approval

- Obtained CE IVD Marks for the CEE-Sure® Blood Collection Tube and the CEE-Sure® Sample Collection Shipping Kit in Europe. These CE Marks confirm that Biocept's CEE-Sure® products, which are specifically designed to collect and transport blood and other liquid biopsy specimens, meet the requirements of the European In-Vitro Diagnostic Devices Directive. These clearances allow Biocept to commercialize its tubes and collection/shipping kits throughout the European Union and other CE Mark geographies.

Industry Conference Presentations

- Presented six posters at the 2019 Association for Molecular Pathology (AMP) Annual Meeting featuring clinical data highlighting Target Selector™ tests and kits. The content of these posters will be published in a future issue of *The Journal of Molecular Diagnostics*.
- Presented data at the 2019 IASLC World Conference on Lung Cancer highlighting the ability of Biocept's circulating tumor DNA (ctDNA) assays to consistently detect actionable biomarkers from the blood of patients diagnosed with lung cancer at a mutant allele frequency as low as 0.01%. The poster featured data from more than 1,400 blood samples drawn from patients diagnosed with non-small cell lung cancer, and collected and shipped using the Company's CEE-Sure® Blood Collection Tubes.
- Presented a poster at the 2019 American Association for Cancer Research Annual Meeting demonstrating the ability of the Target Selector™ assay to detect ESR1 mutations with high sensitivity, resulting in inclusion of the test in a clinical trial sponsored by a major pharmaceutical company.
- Presented a poster at the 2019 San Antonio Breast Cancer Symposium® demonstrating the ability of the Target Selector™ CTC platform to aid in the monitoring and treatment of breast cancer. Study results demonstrated the platform's ability to accurately detect, enumerate and interrogate CTCs in a cohort of more than 1,500 patients, representing various clinical and treatment stages of breast cancer.

Peer-reviewed Journal Publications

- Announced publication of clinical data in *Journal of Clinical Pathology* that further validates Biocept's Target Selector™ qPCR Assay using "Switch Blocker" technology to identify cancer-related mutations in liquid biopsy

samples. Study results showed a very high concordance between Biocept's liquid biopsy testing and tissue biopsy and best-in-class detection of alterations down to a single mutant copy in both analytical and clinical settings.
- Announced publication of case studies in *Clinics in Oncology* demonstrating the clinical utility of Target Selector™ testing in the management of patients diagnosed with advanced non-small cell lung cancer. In each case study, Biocept's liquid biopsy testing detected activating *EGFR* mutations where tissue biopsy was inadequate, and targeted *EGFR*-directed therapy was subsequently administered.
- Announced publication of an article in *PLOS ONE* featuring analytical validation results demonstrating the ultra-sensitive detection of Target Selector™ testing for EGFR, BRAF and KRAS mutations in plasma ctDNA. These tests can be performed in the Company's CLIA laboratory with a commercial turnaround time of only three to four days.

Intellectual Property

- Awarded U.S., Canadian and European patents covering antibody and microchannel technology and enhanced detection of cancer cells. These new patents further expand Biocept's intellectual property estate for capturing and detecting rare cells of interest, including CTCs, to aid in the management of patients with cancer.
- Granted a South Korean patent covering the Target Selector™ oncogene mutation enrichment and detection platform for proprietary Switch-Blocker technology that is core to Target Selector™ assays for molecular analysis using real-time PCR, Sanger sequencing and next-generation sequencing.
- Awarded a patent in China covering methods and devices for the capture of rare cells of interest, including CTCs, that are shed into the bloodstream by solid tumors in which an antibody or mixture of antibodies and a microchannel are used for cell capture, detection and analysis. This patent covers the use of any biological sample type of interest.
- Obtained a patent in Japan covering the use of microchannels for the capture and detection of any target of interest, including proteins and nucleic acids, as well as the capture of cancer or other rare cells that can be used for molecular analysis in blood and other biological fluids.
- Awarded a patent in the U.S. covering devices for the detection of cells of interest, including CTCs that are shed into the bloodstream by solid tumors where an antibody, or mixture of antibodies, and any solid surface are used for cell capture, detection and analysis, including any biological sample type, using single antibodies or cocktails of antibodies.
- Exited 2019 with 37 issued patents globally for Biocept's highly sensitive method of detecting cancer biomarkers.

Corporate Developments

- Promoted Cory J. Dunn, M.S., M. Ed. to Senior Vice President of Commercial Operations. Ms. Dunn joined Biocept as Vice President of Commercial Operations in October 2018.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2019 were $1.8 million, a 108% increase from $859,000 for the fourth quarter of 2018. Revenues for the fourth quarter of 2019 included $1.6 million in commercial test revenue, $87,000 in development services test revenue, and $108,000 in revenue for Target Selector™ RUO kits, which were commercially launched in early 2019, and CEE-Sure® blood collection tubes. Revenues for the fourth quarter of 2018 included $820,000 in commercial test revenues and $39,000 in development services test revenues.

Biocept accessioned 1,159 commercial samples during the fourth quarter of 2019, a 46% increase from the 795 commercial samples accessioned during the fourth quarter of 2018. The Company accessioned 1,278 billable samples during the fourth quarter of 2019, a 36% increase from 938 billable samples during the fourth quarter of 2018.

Cost of revenues for the fourth quarter of 2019 was $2.9 million, compared with $2.4 million for the fourth quarter of 2018. Cost of revenues increased 18% while billable accession volume increased by 36% as the Company continued to leverage its fixed costs.

Research and development (R&D) expenses for the fourth quarter of 2019 were $1.2 million, compared with $1.3 million for the fourth quarter of 2018, with the decrease primarily due to lower allocated cost of laboratory associated activities. General and administrative (G&A) expenses for the fourth quarter of 2019 were $1.9 million, compared with $1.6 million for the fourth quarter of 2018, with the increase due mainly to a reclass of customer service and related expenses from Sales & Marketing to G&A. Sales and marketing (S&M) expenses for the fourth quarter of 2019 were $1.5 million, compared with $1.4 million for the fourth quarter of 2018, with the increase primarily attributed to commissions paid for higher volume and revenue.

The fourth quarter of 2019 included a non-cash deemed dividend of $22,000 for the repricing of adjustable warrants. There was no comparable charge in the fourth quarter of 2018.

The net loss attributable to common shareholders for the fourth quarter of 2019 was $5.7 million, or $0.20 per share on 29.1 million weighted-average shares outstanding. The net loss attributable to common shareholders for the fourth quarter of 2018 was $6.0 million, or $1.43 per share on 4.2 million weighted-average shares outstanding.

Full Year Financial Results

Revenues for 2019 were $5.5 million, a 70% increase from $3.3 million for 2018. Revenues for 2019 included $5.1 million in commercial test revenues, $212,000 in development services test revenues, and $200,000 in revenues for Target Selector™ RUO kits and CEE-Sure® blood collection tubes. Revenues for 2018 included $3.0 million in commercial test revenues and $199,000 in development services test revenues.

Biocept accessioned 4,425 commercial samples during 2019, a 35% increase from the 3,273 commercial samples accessioned during 2018. The Company accessioned 4,976 billable samples during 2019, a 28% increase from 3,896 billable samples during 2018.

Cost of revenues for 2019 was $11.0 million, compared with $10.1 million for 2018. Cost of revenues for 2019 increased 9% while billable accession volume increased by nearly 28%, both compared with 2018.

Total costs and expenses for 2019 were $28.6 million, and included cost of revenues of $11.0 million, R&D expenses of $4.7 million, G&A expenses of $7.0 million and S&M expenses of $5.9 million.

Other expense for 2019 of $2.1 million consisted of non-cash warrant inducement expenses associated with recognizing the fair value of the inducement warrants issued in May 2019 of $1.8 million and $250,000 of interest expense related to equipment finance leases. This compares with other expense for 2018 of $311,000 related to interest expense. Non-cash deemed dividend for the repricing of adjustable warrants for 2019 was of $0.1 million, compared with $0.6 million for 2018.

The net loss attributable to common shareholders for 2019 was $25.3 million, or $1.22 per share on 20.7 million weighted-average shares outstanding. This compares with a net loss attributable to common shareholders for 2018 of $25.2 million, or $9.01 per share on 2.8 million weighted-average shares outstanding. The per-share figures reflect a 1-for-30 reverse split of common stock completed in July 2018.

Biocept reported cash and cash equivalents as of December 31, 2019 of $9.3 million, compared with $3.4 million as of December 31, 2018. The increase includes $25.7 million in net proceeds from equity capital raises conducted in the first and fourth quarters of 2019, and $4.9 million from the exercise of common stock warrants during 2019.

Conference Call and Webcast

Biocept will hold a conference call today at 4:30 p.m. Eastern time to discuss these results and answer questions. The conference call can be accessed by dialing (855) 656-0927 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4109 for other international callers. A live webcast of the conference call will be available on the investor relations page of the company's website at http://ir.biocept.com/events.cfm.

A replay of the call will be available for 48 hours following its conclusion and can be accessed by dialing (877) 344-7529 for domestic callers, (855) 669-9658 for Canadian callers or (412) 317-0088 for other international callers. Please use event passcode 10140336. A replay of the webcast will be available for 90 days.

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 CTCs and in 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 news 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 be 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 news release are not strictly historical, including, without limitation, statements as to our ability to provide physicians with clinically actionable information to improve the outcomes of cancer patients, our ability to continue to see benefits from our automation efforts, our ability to grow our business and drive adoption of our products, and our expectation of continued growth in the uro-oncology business segment, 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 news 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 at http://www.sec.gov/.

Investor Contact:
LHA Investor Relations
Jody Cain
Jcain@lhai.com
(310) 691-7100

Media:
CORE IR
Jules Abraham
julesa@coreir.com
917-885-7378

BIOCEPT, INC.
CONDENSED BALANCE SHEETS

	December 31, 2018	December 31, 2019 (unaudited)
ASSETS		
Cash	$ 3,423,373	$ 9,301,406
Accounts receivable, net	1,574,325	3,527,078
Inventories, net	587,222	767,986
Prepaid expenses and other current assets	425,961	296,127
TOTAL CURRENT ASSETS	6,010,881	13,892,597
FIXED ASSETS, NET	2,739,422	1,504,330
LEASE RIGHT-OF-USE ASSETS	—	2,335,717
TOTAL ASSETS	$ 8,750,303	$ 17,732,644
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	$ 4,609,647	$ 5,558,812
NON-CURRENT LIABILITIES, NET	1,098,137	973,189
TOTAL LIABILITIES	5,707,784	6,532,001
SHAREHOLDERS' EQUITY	3,042,519	11,200,643
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 8,750,303	$ 17,732,644

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended December 31,		For the year ended December 31,	
	2018 (unaudited)	2019 (unaudited)	2018	2019
NET REVENUES	$ 859,526	$ 1,783,742	$ 3,250,298	$ 5,528,566
COSTS AND EXPENSES				
Cost of revenues	$ 2,435,262	$ 2,872,098	$ 10,051,735	$ 10,977,520
Research and development expenses	1,288,957	1,161,905	4,468,572	4,697,022
General and administrative expenses	1,632,670	1,911,593	7,074,024	6,970,120
Sales and marketing expenses	1,440,798	1,489,216	5,914,706	5,940,843
Total costs and expenses	6,797,687	7,434,812	27,509,037	28,585,505
LOSS FROM OPERATIONS	(5,938,161)	(5,651,070)	(24,258,739)	(23,056,939)
INTEREST AND OTHER INCOME/(EXPENSE), NET	(74,265)	(62,408)	(310,976)	(2,081,100)
LOSS BEFORE INCOME TAXES	(6,012,426)	(5,713,478)	(24,569,715)	(25,138,039)
INCOME TAXES	(1,886)	—	(1,886)	—
NET LOSS AND COMPREHENSIVE LOSS	$ (6,014,312)	$ (5,713,478)	$ (24,571,601)	$ (25,138,039)
Deemed dividend related to warrants down round provision	—	(21,829)	(636,370)	(121,572)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (6,014,312)	$ (5,735,307)	$ (25,207,971)	$ (25,259,611)
NET LOSS PER SHARE				
- Basic	$ (1.43)	$ (0.20)	$ (9.01)	$ (1.22)
- Diluted	$ (1.43)	$ (0.20)	$ (9.01)	$ (1.22)
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING				
- Basic	4,209,221	29,128,632	2,798,243	20,660,894
- Diluted	4,209,221	29,128,632	2,798,243	20,660,894

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