

Biocept

Completing the Answer™

Biocept Reports First Quarter 2020 Financial Results

May 13, 2020

Revenues of \$1.4 million increased 41%, revenue per accession increased 27%
Conference call begins at 4:30 p.m. Eastern time today

SAN DIEGO, May 13, 2020 /PRNewswire/ -- [Biocept, Inc.](#) (NASDAQ: BIOC), a leading provider of molecular technologies designed to provide physicians with clinically actionable information to improve the outcomes of patients diagnosed with cancer, reports financial results for the three months ended March 31, 2020 and provides an update on its business progress.



"Revenue for the first quarter was \$1.4 million, representing a 41% increase over the prior-year period driven by a 27% increase in revenue per commercial accession," said Michael Nall, President and CEO of Biocept. "We increased revenues even with the headwinds of the COVID-19 pandemic, which we estimate led to an approximate 15-25% decline in commercial volume from current customers and also impacted opportunities for us to gain new customers with the closing of many physician offices and labs. Operational efficiencies contributed to progress toward our goal of positive gross margin resulting in a 50 percentage point improvement versus the prior-year period. These efficiencies are primarily related to automation of our lab, with additional actions yet to be taken this year.

"Importantly, we believe we are well positioned to weather the pandemic, which is impacting testing volume industrywide, and for a return to growth as shelter-in-place restrictions are lifted and physician offices and labs reopen," he added. "We are an established leader in liquid biopsy and our Target Selector™ assays and products provide critical information to physicians in treatment decision-making. We expect that when it is safe for patients diagnosed with cancer to continue to seek treatment, our commercial volume will return to a more normal level. We are particularly pleased with our strengthened balance sheet, having raised approximately \$36.3 million in net proceeds since the beginning of December 2019. While we believe that based on historical and planned cash usage, our current funding is expected to support operations through most of 2021; however, with the uncertainty introduced by the impact of COVID-19 on revenue and collections, our cash runway may be shorter."

First Quarter 2020 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, up to 30% and 36%, respectively, will develop brain metastases. The validations study for our 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 the availability of research-use-only (RUO) kits that allow molecular laboratories worldwide to detect oncogene mutations through the analysis of both Formalin-Fixed Paraffin-Embedded (FFPE) tissue gained from surgical biopsies as well as circulating tumor DNA (ctDNA) gained from blood-based liquid biopsies. The first RUO kit with the ability to use tissue and liquid biopsy samples is designed for the detection of EGFR mutations that are among the most frequently evaluated biomarkers of lung cancer. RUO kits for other oncogene mutations are planned for future launches.
- Awarded CE-IVD Mark for the Target Selector™ molecular assay EGFR Kit. The CE Mark confirms that Target Selector™ kits meet the requirements of the European In-Vitro Diagnostic Devices Directive and allows Biocept to commercialize these kits throughout the European Union and other CE Mark geographies. Molecular assay kits detect key oncogene mutations through the analysis of both FFPE tissue as well as ctDNA. The EGFR pathway can include mutations that are among the most frequently evaluated biomarkers for lung cancer.
- Announced the validation for COVID-19 testing. Biocept operates a high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory in San Diego, with specialized, licensed molecular lab staff who have been trained in performing the COVID-19 testing. The lab will be using ThermoFisher Scientific's FDA-approved for EUA (Emergency Use Authorization) testing TaqPath™ molecular diagnostic platform and kit for SARS-CoV-2 (COVID-19). Due to the national shortage, Biocept's clients have had difficulty gaining specimen collection kits to send to Biocept for testing and to date, we have not been able to perform any COVID 19 testing. In order to address this and provide needed testing, Biocept intends to manufacture its own collection kits for distribution to clients and expects those kits to be available in June.

Commercial Agreements

- Signed laboratory services agreements with two large California-based independent physician associations (IPAs) to provide Biocept's Target Selector™ liquid biopsy testing services.

Peer-reviewed Journal Publications

- Announced publication of clinical data in the *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.

Intellectual Property

- Awarded U.S. patent covering antibody and microchannel technology and enhanced detection of cancer cells. This new patent expands 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 Australian and Brazilian patents providing intellectual property protection for its Primer Switch technology that is useful for ctDNA analysis using reverse-transcription PCR and associated methods, including next-generation sequencing (NGS).

Corporate Developments

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

First Quarter Financial Results

Revenues for the first quarter of 2020 were \$1.4 million, a 41% increase from \$1.0 million for the first quarter of 2019. Revenues for the first quarter of 2020 included \$1.3 million in commercial test revenue, \$60,000 in development services test revenue, and \$69,000 in revenue for distributed products, Target Selector™ RUO kits and CEE-Sure® blood collection tubes. Revenues for the first quarter of 2019 include \$976,000 in commercial test revenues, \$42,000 in development services test revenues and \$5,000 from RUO kits and blood collection tubes.

Biocept accessioned 1,306 total samples during the first quarter of 2020, compared with 1,325 total samples during the first quarter of 2019. The Company accessioned 1,141 billable samples during the first quarter of 2020 compared with 1,155 billable samples during the first quarter of 2019. We believe that the decline in total samples and billable samples was due to the impact of the COVID-19 pandemic.

Cost of revenues for the first quarter of 2020 was \$2.9 million, compared with \$2.6 million for the first quarter of 2019. Cost of revenues increased 13% while revenues increased by 41% as Biocept continued to leverage its fixed costs.

Research and development (R&D) expenses for the first quarter of 2020 were \$1.3 million, compared with \$1.2 million for the first quarter of 2019, with the increase primarily due to development and validation costs related to additional offerings, such as validation

of CSF and COVID-19 assays. General and administrative (G&A) expenses for the first quarter of 2020 were \$1.9 million, compared with \$1.7 million for the first quarter of 2019, with the increase due mainly to a reclassification of certain customer service and related expenses from sales and marketing to G&A. Sales and marketing expenses for the first quarter of 2020 were \$1.5 million, compared with \$1.4 million for the first quarter of 2019, with the increase primarily attributed to commission on higher revenue.

Other expense, net for the first quarter of 2020 was \$2.2 million, compared with \$62,000 for the first quarter of 2019, with the increase mainly due to \$2.1 million in warrant inducement expense. In January 2020, Biocept completed a Warrant Exercise Inducement offering for net proceeds of approximately \$2.3 million.

The net loss attributable to common shareholders for the first quarter of 2020 was \$8.3 million, or \$0.11 per share on 79.0 million weighted-average shares outstanding and included \$2.1 million in non-cash warrant inducement expense and the impact of the COVID-19 pandemic. The net loss attributable to common shareholders for the first quarter of 2019 was \$6.0 million, or \$0.61 per share on 9.8 million weighted-average shares outstanding.

Biocept reported cash and cash equivalents as of March 31, 2020 of \$21.5 million, compared with \$9.3 million as of December 31, 2019. The increase included approximately \$17.7 million in net proceeds from two registered direct offerings and the over allotment of warrants from a December 2019 financing. In April 2020, the Company raised net proceeds of approximately \$9.6 million from a registered direct offering.

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 10143445. 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 weather the COVID-19 pandemic and return commercial volume to normal levels and grow our business following the lifting of shelter-in-place restrictions, our ability to launch additional RUO kits for other oncogene mutations, and our ability to provide COVID-19 testing, 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>.

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BIOCEPT, INC. CONDENSED BALANCE SHEETS

	December 31, 2019	March 31, 2020
	(unaudited)	
ASSETS		
Cash	\$ 9,301,406	\$ 21,493,192
Accounts receivable, net	3,527,078	3,418,897
Inventories, net	767,986	918,698
Prepaid expenses and other current assets	296,127	429,131
TOTAL CURRENT ASSETS	13,892,597	26,259,918
FIXED ASSETS, NET	1,504,330	1,463,128
LEASE RIGHT-OF-USE ASSETS	2,335,717	2,089,284
TOTAL ASSETS	\$ 17,732,644	\$ 29,812,330
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	\$ 5,558,812	\$ 6,031,796
NON-CURRENT LIABILITIES, NET	973,189	1,050,429
TOTAL LIABILITIES	6,532,001	7,082,225
SHAREHOLDERS' EQUITY	11,200,643	22,730,105
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 17,732,644	\$ 29,812,330

BIOCEPT, INC. CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended March 31,	
	2019 (unaudited)	2020 (unaudited)
NET REVENUES	\$ 1,024,239	\$ 1,446,549
COSTS AND EXPENSES		
Cost of revenues	\$ 2,599,364	\$ 2,946,858
Research and development expenses	1,223,291	1,312,676
General and administrative expenses	1,681,837	1,904,433
Sales and marketing expenses	1,374,560	1,465,115
Total costs and expenses	6,879,052	7,629,082
LOSS FROM OPERATIONS	(5,854,813)	(6,182,533)
INTEREST AND OTHER INCOME/(EXPENSE), NET	(61,974)	(2,158,805)
LOSS BEFORE INCOME TAXES	(5,916,787)	(8,341,338)
INCOME TAXES	—	—
NET LOSS AND COMPREHENSIVE LOSS	\$ (5,916,787)	\$ (8,341,338)
Deemed dividend related to warrants down round provision	(99,743)	(2,774)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ (6,016,530)	\$ (8,344,112)
NET LOSS PER SHARE		
- Basic	\$ (0.61)	\$ (0.11)
- Diluted	\$ (0.61)	\$ (0.11)
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING		
- Basic	9,792,093	78,999,924
- Diluted	9,792,093	78,999,924

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