Biocept Reports First Quarter 2021 Financial Results

May 12, 2021

- *Revenues of $17.8 million were driven by RT-PCR COVID-19 testing*
- *Initiated full commercial launch of CNSide™ cerebrospinal fluid assay for diagnosing and managing patients with metastatic cancer involving the central nervous system*
- *Received approximately 390,000 COVID-19 samples since June 2020*
- *Hosted KOL webinar with leading neuro-oncologists discussing their use of CNSide and its importance in clinical decisions that affect patient outcomes*

Conference call begins at 4:30 p.m. Eastern time today

SAN DIEGO--(BUSINESS WIRE)--May 12, 2021-- Biocept, Inc. (Nasdaq: BIOC), a leading provider of molecular diagnostic assays, products and services, reports financial results for the three months ended March 31, 2021 and provides a business update.

“We are reporting profitability for the second consecutive quarter on revenues of $17.8 million, as our dedicated Biocept team continued to serve our community with COVID-19 RT-PCR testing featuring exceptional customer service and rapid turnaround times,” said Michael Nall, Biocept’s President and CEO. “These outstanding financial results support further advancements with our core oncology business and more specifically our focus on neuro-oncology as we build for a strong long-term future.

“The full commercial launch of CNSide, our cerebrospinal fluid assay detecting tumor cells and molecular biomarkers, is transformational for Biocept,” he added. “We developed CNSide to address a high unmet medical need by providing diagnostic testing that we believe exceeds the capabilities of the current standard of care, CSF cytology. In early studies, CNSide has shown better sensitivity than CSF cytology in detecting patients with metastatic cancer involving the central nervous system. CNSide has the added advantage of providing quantitative results, which is showing promise in assessing patient response to therapy and monitoring patients for minimal residual disease.

“We are pursuing a clinical strategy to support CNSide as the new standard-of-care diagnostic for cancer that has metastasized to the central nervous system. We also are expanding our reach to neuro-oncologists, medical oncologists and other physicians to build upon the positive reception our assay has received from early adopters. Following our soft launch in early 2020, we have seen CNSide orders increase quarterly with many physicians ordering repeatedly. We recently hosted a highly informative webinar in which three neuro-oncology leaders using our CNSide assay in their practices cited multiple case studies with favorable patient outcomes,” he added. “This is an exciting opportunity for Biocept to help patients with breast and lung cancers that have metastasized to the central nervous system—a U.S. market we estimate at more than $1 billion annually.

“I’m exceptionally proud of the Biocept team for stepping up to address the pressing public health need for COVID-19 testing,” said Mr. Nall. “Since we began offering this service in 2020, we have received approximately 390,000 samples, including about 140,000 samples during the first quarter. We recently announced a partnership to make our service available to all 116 California community colleges including their 2.1 million students, as well as faculty and staff. We expect COVID-19 testing will continue to be an important component of our business and provide meaningful revenues throughout 2021, noting our expectations might change as the pandemic evolves.”

First Quarter 2021 and Recent Highlights

Commercial Launches, Developments and Agreements

Oncology

- Initiated the full commercial launch of CNSide, Biocept’s cerebrospinal fluid assay that offers a timely and accurate method to diagnose patients with lung and breast cancer that has metastasized to the central nervous system, along with the ability to identify actionable biomarkers and assess a patient’s response to therapy. CNSide is based on Biocept’s proprietary quantitative tumor cell capture and detection method paired with assays to identify actionable molecular treatment targets.
- Established a collaboration with Protean BioDiagnostics, an independent pathology laboratory, to evaluate the ability of the novel Target Selector™ research use only (RUO) kits to determine EGFR status in patients with non-small cell lung cancer (NSCLC) comparing circulating tumor DNA (ctDNA) from blood with formalin-fixed paraformaldehyde embedded (FFPE) tissue samples. Protean BioDiagnostics also expects to validate the analytical performance of a laboratory developed test (LDT) based on Biocept’s EGFR assay test kit in accordance with the requirements of the College of American Pathologists (CAP) validation process.

COVID-19

- Partnered with the Foundation for California Community Colleges to make Biocept's COVID-19 testing available for purchase and use with more than 2.1 million students, as well as faculty and staff through the Foundation's CollegeBuys program. The availability of COVID-19 testing is expected to provide information needed to help protect the safety of campus populations and reduce the spread of the SARS-CoV-2 virus as students return to campus from the current remote learning environment.
- Received approximately 390,000 samples for COVID-19 RT-PCR testing at Biocept's high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory since beginning to offer this testing in 2020. The lab is using Thermo Fisher Scientific's FDA-approved for EUA testing TaqPath™ molecular diagnostic platform and kit. The vast majority of test results to date have been reported to healthcare providers within 48 hours of sample receipt.
- Entered into development and supply agreements with Aegea Biotechnologies following success under Biocept's first agreement with Aegea to develop a new, highly sensitive quantitative PCR-based COVID-19 assay. The new assay utilizes the patented Switch-Blocker™ technology, which is also used in Biocept's Target Selector assays. Under the supply agreement, Aegea is supplying the COVID-19 assay kit for validation in Biocept's lab. Following validation, Biocept intends to commercialize an LDT. The assay is designed for quantitative monitoring of viral RNA load to better assist healthcare providers in screening and managing patients.

Clinical Study

- Announced plan to initiate a clinical validation study, the 4C trial, evaluating the performance of the CNSide assay compared with current standard of care, which includes imaging, CSF cytology and clinical evaluation of patients with suspected cancer metastasis involving the central nervous system. This study and our planned application for FDA breakthrough device designation will support the Company's efforts to introduce an FDA-cleared class II IVD product.

Industry Presentations and Publication

- Hosted a neuro-oncology webinar discussing CNSide for the diagnosis of cancer involving the central nervous system. The webinar featured a technology overview and leading neuro-oncologists citing case studies using the CNSide assay with subsequent favorable patient outcomes.
- Presented a poster with colleagues from NeoGenomics Laboratories (Nasdaq: NEO) at the Molecular Med Tri-Con Virtual Conference showing Biocept's Target Selector molecular assay kit detected mutations in up to 50% of tissue biopsy specimens from patients diagnosed with NSCLC that were deemed quantity not sufficient (QNS) due to a lack of tissue to perform testing. The assay was used to evaluate the presence of several key EGFR and KRAS mutations in FFPE biopsy samples that had inadequate tumor for next-generation sequencing (NGS) analysis.

First Quarter Financial Results

Revenues for the first quarter of 2021 were $17.8 million, compared with $1.4 million for the first quarter of 2020, with the increase attributable to RT-PCR COVID-19 testing. Revenues for the first quarter of 2021 included $17.7 million in commercial test revenue, which is comprised of $16.8 million attributable to RT-PCR COVID-19 testing, $39,000 in development services test revenue and $62,000 in revenue from distributed products, Target Selector RUO kits, CEE-Sure® blood collection tubes and payments from Aegea Biotechnologies for services associated with the development of a COVID-19 assay. 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 Target Selector RUO kits and CEE-Sure blood collection tubes.

Biocept accessioned 145,110 total samples during the first quarter of 2021, compared with 1,306 total samples during the first quarter of 2020. The Company accessioned 144,932 commercial billable samples during the first quarter of 2021, compared with 985 commercial billable samples during the first quarter of 2020. The increase in total and commercial billable samples was primarily attributable to COVID-19 testing.

Cost of revenues for the first quarter of 2021 was $9.0 million, compared with $2.9 million for the first quarter of 2020, with the increase primarily due to COVID-19-related collection kits and consumable expenses. Research and development (R&D) expenses for the first quarter of 2021 were $1.0 million, compared with $1.3 million for the first quarter of 2020, with the decrease primarily attributable to lower facilities costs and cost of revenue allocations to R&D. General and administrative (G&A) expenses for the first quarter of 2021 were $3.1 million, compared with $1.9 million for the first quarter of 2020, with the increase primarily due to headcount additions and other expenses related to COVID-19 testing. Sales and marketing expenses for the first quarter of 2021 were $1.9 million, compared with $1.5 million for the first quarter of 2020, with the increase resulting from higher sales commissions due to higher revenues.

Operating income for the first quarter of 2021 was $2.7 million, versus an operating loss of $6.2 million for the first quarter of 2020.

Other expense, net for the first quarter of 2021 was $65,000, compared with other expense, net for the first quarter of 2020 of $2.2 million, with the decrease mainly due to $2.1 million in warrant inducement expense in the first quarter of 2020.

Net income attributable to common shareholders for the first quarter of 2021 was $2.6 million, or $0.19 per diluted share on 13.7 million weighted-average shares outstanding. This compares with a net loss attributable to common shareholders for the first quarter of 2020 of $8.3 million, or $1.06 per diluted share on 7.9 million weighted-average shares outstanding. The change in outstanding share count reflects the 1-for-10 reverse split of common stock effected in September 2020.

Biocept reported cash and cash equivalents as of March 31, 2021 of $14.2 million, compared with $14.4 million as of December 31, 2020.

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 10155314. A replay of the webcast will be available for 90 days.

About Biocept

Biocept, Inc. develops and commercializes molecular diagnostic assays that provide physicians with clinically actionable information for treating and monitoring patients diagnosed with a variety of cancers. In addition to its broad portfolio of blood-based liquid biopsy assays, Biocept has developed the CNSide™ cerebrospinal fluid assay that detects cancer that has metastasized to the central nervous system. Biocept's patented Target Selector™ technology captures and quantitatively analyzes CSF tumor cells for tumor-associated molecular markers, using technology first developed for use in blood. Biocept also is leveraging its molecular diagnostic capabilities to offer nationwide COVID-19 RT-PCR testing to support public health efforts during this unprecedented pandemic. For more information, visit www.biocept.com. Follow Biocept on Facebook, LinkedIn and Twitter.

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 the ability of our assays to uniquely address a high unmet clinical need by identifying metastatic progression of cancer to the central nervous system and brain, our ability to establish our assays as the standard of care in diagnosing cancer with central nervous system involvement, the extent to which COVID-19 testing will continue to be an important component of our business and provide meaningful revenues throughout 2021, and our ability to validate and commercialize the COVID-19 assay kit co-developed with Aegea Biotechnologies, 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/.

BIOCEPT, INC.

CONDENSED BALANCE SHEETS

	December 31, 2020	March 31, 2021 (unaudited)
ASSETS		
Cash	$ 14,367,942	$ 14,197,547
Accounts receivable, net	14,144,911	17,143,572
Inventories, net	1,929,624	3,258,594
Prepaid expenses and other current assets	2,151,527	697,724
TOTAL CURRENT ASSETS	32,594,004	35,297,437
FIXED ASSETS, NET	2,317,616	2,095,704
LEASE RIGHT-OF-USE ASSETS	12,114,058	12,466,926
OTHER NON-CURRENT ASSETS	425,908	438,776

TOTAL ASSETS	$ 47,451,586	$ 50,298,843
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES, NET	$ 12,494,253	$ 11,913,007
NON-CURRENT LIABILITIES, NET	11,264,911	11,614,609
TOTAL LIABILITIES	23,759,164	23,527,616
SHAREHOLDERS' EQUITY	23,692,422	26,771,227
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 47,451,586	$ 50,298,843

BIOCEPT, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended March 31,	
	2020	**2021**
	(unaudited)	**(unaudited)**
NET REVENUES	$ 1,446,549	$ 17,756,190
COSTS AND EXPENSES		
Cost of revenues	$ 2,946,858	$ 9,005,856
Research and development expenses	1,312,676	1,042,725
General and administrative expenses	1,904,433	3,119,804
Sales and marketing expenses	1,465,115	1,923,272
Total costs and expenses	7,629,082	15,091,657
(LOSS)/INCOME FROM OPERATIONS	(6,182,533)	2,664,533
INTEREST AND OTHER INCOME/(EXPENSE), NET	(2,158,805)	(65,241)
(LOSS)/INCOME BEFORE INCOME TAXES	(8,341,338)	2,599,292
INCOME TAXES	—	—
NET (LOSS)/INCOME AND COMPREHENSIVE LOSS	$ (8,341,338)	$ 2,599,292
Deemed dividend related to warrants down round provision	(2,774)	—
NET (LOSS)/INCOME ATTRIBUTABLE TO COMMON SHAREHOLDERS	(8,344,112)	2,599,292
NET (LOSS)/INCOME PER SHARE		

- Basic	$ (1.06)	$ 0.19
- Diluted	$ (1.06)	$ 0.19
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING		
- Basic	7,899,991	13,400,007
- Diluted	7,899,991	13,667,716

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