

# **Biocept Reports Second Quarter 2015 Financial Results**

Significantly Increases Sample Volume and Number of Biomarker Assays per Sample

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

SAN DIEGO--(BUSINESS WIRE)-- Biocept, Inc. (NASDAQ: BIOC), a molecular diagnostics company commercializing and developing liquid biopsies to improve the diagnosis and treatment of cancer, today reported financial results for the three and six months ended June 30, 2015.

"We are proud to have achieved increased results in multiple key operational metrics during the second quarter," said Michael W. Nall, President and CEO of Biocept. "Total sample volume, which includes commercial, development and research assays, grew by 46% to 525 during the second quarter of 2015 from 359 during the first quarter of 2015. We also increased the number of biomarkers tested per sample, which is a direct result of the expansion of our portfolio of commercially available biomarkers. A change in CPT codes early this year, however, caused a delay in reimbursement payments, which impacted quarterly revenues. We believe that we have resolved the reimbursement issue and expect to receive additional revenues from resubmitted claims beginning in the third quarter."

Among recent developments, Biocept launched proprietary quantitative assays that target important mutations in colorectal cancer, melanoma and small cell lung cancer - all new biomarker assays for Biocept - while building upon what the company believes to be the largest number of commercial biomarker assays for clinical use of any company offering liquid biopsies. Biocept is working toward additional validation for its liquid biopsy approach through new collaborations, and is increasing physician awareness and adoption with featured presentations at important medical conferences.

"Biocept is among the few companies with liquid biopsy assays in the commercial stage and we are excited about our future as a leader in an emerging market that is rapidly becoming standard of care," added Mr. Nall. "Our biomarker assays feature high specificity and sensitivity, making them ideal for cancer detection as well as monitoring, and we offer two highly validated liquid biopsy approaches with assays for both CTC and ctDNA. We are executing well on our business strategy and have a strong balance sheet to support our growth initiatives. Importantly we are committed to positively impacting patient care and reducing the cost of healthcare."

#### Second Quarter and Recent Operational Highlights

#### Commercial Biomarker Launches

- Launched the Target Selector<sup>™</sup> assay for KRAS mutations, expanding Biocept's commercially launched biomarker assays to include colorectal cancer and increasing biomarker detection for other solid tumors.
- Launched the Target Selector<sup>™</sup> assay for BRAF mutations, expanding Biocept's commercial assays to include melanoma and increasing biomarker detection for other solid tumors.
- Expanded our blood-based biomarker assay menu with FGFR1 amplification, which has been identified in breast cancer and in both small cell and non-small cell lung cancers.

#### Collaborations

- Entered into a research and commercial collaboration with Sarah Cannon Research Institute, the global cancer enterprise of Hospital Corporation of America, to expand the clinical utility of Biocept's CTC and ctDNA testing for detecting estrogen positive (ER+) breast cancer. The ability to detect ER+ will help in identifying patients who qualify for new, targeted drug therapies.
- Announced the addition of Dr. Marileila Varella Garcia from the University of Colorado at Denver, an expert in the molecular and cytogenetic analysis of cancer, as a Scientific Advisor to the company.

#### Patent

• Received a U.S. patent for the company's blood collection and transport preservative, which are key elements in Biocept's microchannel technology for using CTC and ctDNA predictive and prognostic genomic analysis.

#### Industry Conferences

- Announced that our collaborator Hatim Husain, MD, from the Moores Cancer Center at University of California San Diego, and Biocept Chief Scientific Officer Lyle Arnold, Ph.D., will present at the Next Generation Dx Summit discussing use of liquid biopsies to identify PDL-1 and CMET expression in lung cancer. Checkpoint inhibition with anti-PD1 and anti-PDL1 antibodies is a significant component of the predictive markers for lung cancer.
- Presented an abstract, along with our collaborator, Lyudmila Bazhenova, MD from the Moores Cancer Center at University of California San Diego, at the American Society of Clinical Oncology (ASCO) annual meeting demonstrating continued evidence of the clinical utility in non-small cell lung cancer of Biocept's liquid biopsy assays.

## **Second Quarter Financial Results**

Biocept accessioned 336 commercial cases during the second quarter of 2015, up from three commercial cases during the second quarter of 2014. Development services case volume grew to 50 in the second quarter of 2015 compared to 39 development services assays performed in the second quarter of 2014.

Revenues for the second quarter of 2015 increased 305% to \$77,000 from \$19,000 for the second quarter of 2014. This growth included a \$60,000 increase in commercial assay revenues primarily from higher commercial assay volume. Revenues for development services assays remained relatively unchanged in the second quarters of 2015 and 2014, respectively. Revenues from commercial cases are recognized as payment is collected, which can extend beyond the end of the quarter in which the cases were accessioned. The average reimbursement collected from third-party payors for cases billed from July through December, 2014 was \$612.

Cost of revenues was \$985,000 for the second quarter of 2015, compared with \$359,000 for the second quarter of 2014. Higher cost of revenues during the second quarter of 2015 was attributable primarily to a \$338,000 increase related to the greater proportion of laboratory costs charged to cost of revenues as a result of increased sample volume related to commercial activities and a \$228,000 increase in personnel and materials costs primarily related to higher assay volume.

Research and development (R&D) expenses for the second quarter of 2015 decreased 30% to \$772,000 from \$1.1 million for the same period in 2014, with the decline due primarily to the lower proportion of laboratory costs charged to R&D as a result of decreased sample volume related to R&D activities.

General and administrative (G&A) expenses for the second quarter of 2015 were \$1.4 million, compared with \$1.0 million for the same period in 2014. The increase was primarily due to higher personnel and service provider costs related to being a publicly traded company, as well as an increase in allocated facility costs.

Sales and marketing expenses for the second quarter of 2015 were \$851,000, compared with \$423,000 for the second quarter of 2014, with the increase primarily due to higher personnel-related expenses resulting from the deployment of the Company's sales and marketing organization. During the second quarter of 2015 Biocept had an average of 11 employees in sales and marketing, compared with four employees in the sales and marketing function during the second quarter of 2014.

The net loss for the second quarter of 2015 was \$4.0 million, or \$0.22 per share based on 18.0 million weighted-average shares outstanding. This compared with a net loss of \$3.0 million, or \$0.67 per share based on 4.4 million weighted-average shares outstanding, for the second quarter of 2014. The increase in net loss was primarily due to higher expenses associated with increased sample volume and expansion of the sales and marketing organization.

## **Six Month Financial Results**

Biocept accessioned 583 commercial assays during the first six months of 2015, up from 14 during the prior-year period. Revenues for the first six months of 2015 increased by \$179,000 to \$227,000 compared with the prior year period. Cost of revenues for the first six months of 2015 was \$1.8 million compared with \$1.0 million for the first six months of 2014, with the increase attributable primarily to higher commercial assay volume, partially offset by non-recurring personnel costs related to the company's IPO in February 2014.

Total operating expenses were \$5.9 million for the first six months of 2015 compared with \$5.5 million in the prior-year period, with the increase attributable to higher sales and marketing expenses primarily due to the deployment of the sales organization, offset by a decrease in R&D expenses due to the lower proportion of laboratory costs charged to R&D as a result of decreased sample volume related to R&D activities and a decrease in G&A expenses related mainly to non-recurring personnel costs associated with the IPO in the prior-year period.

The net loss for the first six months of 2015 was \$7.8 million, or \$0.55 per share based on 14.2 million weighted-average shares outstanding, compared with a net loss of \$8.1 million, or \$2.30 per share based on 3.5 million weighted-average shares

#### outstanding.

Biocept reported cash and cash equivalents of \$16.5 million as of June 30, 2015, compared with \$5.4 million as of December 31, 2014. In February 2015, the company completed a follow-on offering of common stock and warrants that, together with the subsequent exercise of such warrants, has raised net proceeds to the company of \$18.5 million.

## **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 (877) 407-4018 for domestic callers or (201) 689-8471 for international callers. A live webcast of the conference call will be available on the investor relations page of the Company's corporate website at <a href="http://ir.biocept.com/events.cfm">http://ir.biocept.com/events.cfm</a>. The webcast will be available for 90 days.

A replay of the call will be available for 48 hours following the conclusion of the call by dialing (877) 870-5176 for domestic callers and (858) 384-5517 for international callers. Please use event passcode 13615125.

## **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 technology platform captures and analyzes circulating tumor DNA, both in CTCs and in plasma (ctDNA). Biocept currently offers biomarker assays for Lung, Breast, Colorectal, and Gastric Cancers as well as Melanoma. The company plans to introduce CLIA-validated assays for prostate and other solid tumors in the near term.

#### 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 improvement of clinical outcomes, the resolution of issued related to reimbursement, our impact on diagnostic standard of care and healthcare costs, and our ability to advance our commercial strategy and further enhance our product portfolio, 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 are advised to review our filings with the SEC at <u>www.sec.gov</u>.

# Biocept, Inc. CONDENSED BALANCE SHEETS

	December 31,		June 30,	
		2014	2015	
			(unaudited)	
ASSETS				
Cash and cash equivalents	\$	5,364,582	\$16,523,975	
Accounts receivable		10,600	32,060	
Inventories, net		188,728	253,864	
Prepaid expenses and other current assets		338,721	589,573	
TOTAL CURRENT ASSETS		5,902,631	17,399,472	
FIXED ASSETS, NET		662,422	918,187	
TOTAL ASSETS	\$	6,565,053	\$18,317,659	
LIABILITIES AND SHAREHOLDERS' EQUITY/(DEFICIT)				
CURRENT LIABILITIES	\$	1,430,783	\$ 3,033,146	
NON-CURRENT LIABILITIES, NET		5,354,839	4,234,552	
TOTAL LIABILITIES		6,785,622	7,267,698	
SHAREHOLDERS' EQUITY/(DEFICIT)		(220,569)	11,049,961	

# Biocept, Inc. CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

	For the three months ended June 30				For the six months ended June 30,				
		2014		2015		2014		2015	
REVENUES	\$	19,245	\$	76,768	\$	47,520	\$	226,770	
COST OF REVENUES		359,364		985,219		1,017,679		1,842,192	
GROSS LOSS		(340,119)		(908,451)		(970,159)		(1,615,422)	
OPERATING EXPENSES									
Research and development		1,107,678		772,098		2,116,607		1,714,227	
General and administrative		1,032,855		1,359,226		2,909,767		2,651,275	
Sales and marketing		423,361		851,109		434,503		1,560,565	
Total operating expenses		2,563,894		2,982,433		5,460,877		5,926,067	
LOSS FROM OPERATIONS		(2,904,013)		(3,890,884)		(6,431,036)		(7,541,489)	
INTEREST AND OTHER INCOME/									
(EXPENSE), NET		(92,027)		(143,866)		(1,692,875)		(293,065)	
LOSS BEFORE INCOME TAXES		(2,996,040)		(4,034,750)		(8,123,911)		(7,834,554)	
INCOME TAXES		(800)		(355)		(800)		(1,279)	
NET LOSS & COMPREHENSIVE LOSS	\$	(2,996,840)	\$	(4,035,105)	\$	(8,124,711)	\$	(7,835,833)	
NET LOSS PER SHARE									
- Basic	\$	(0.67)	\$	(0.22)	\$	(2.30)	\$	(0.55)	
- Diluted	\$	(0.67)	\$	(0.22)	\$	(2.30)	\$	(0.55)	
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING									
- Basic		4,449,603		17,998,969		3,538,503		14,206,885	
- Diluted		4,449,603		17,998,969		3,538,503		14,206,885	

View source version on businesswire.com: http://www.businesswire.com/news/home/20150810006120/en/

**Investor Contact:** 

LHA Jody Cain 310-691-7100 jcain@lhai.com

Source: Biocept, Inc.

News Provided by Acquire Media