

BIOCEPT INC

FORM 8-K (Current report filing)

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Address	5810 NANCY RIDGE DR SAN DIEGO, CA 92121
Telephone	858-320-8200
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Symbol	BIOC
SIC Code	8071 - Medical Laboratories
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 7, 2017

BIOCEPT, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36284
(Commission
File Number)

80-0943522
(I.R.S. Employer
Identification No.)

5810 Nancy Ridge Drive, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 320-8200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On March 7, 2017, we issued a press release announcing our financial results for the three months and year ended December 31, 2016. A copy of the press release and accompanying information is attached as Exhibit 99.1 to this current report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this current report shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission, whether filed before or after the date hereof regardless of any general incorporation language in any such filing, unless we expressly set forth in such filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated March 7, 2017

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 7, 2017

BIOCEPT, INC.

By: /s/ Timothy C. Kennedy

Name: Timothy C. Kennedy

Title: Chief Financial Officer, Senior Vice President of
Operations and Corporate Secretary

Biocept Reports Fourth Quarter and Full Year 2016 Financial Results

Revenues increased more than five-fold in 2016 and nearly six-fold in the fourth quarter of 2016

Company to host conference call at 4:30 p.m. Eastern time today

SAN DIEGO (March 7, 2017) – 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 months and the full year ended December 31, 2016, and provides an update on business progress.

“We made great progress in 2016 and ended the year on a high note, with revenues and new account start-ups reaching the highest levels of any quarter in 2016,” said Michael Nall, President and CEO of Biocept. “Despite the impact of fourth quarter seasonality, our revenues for the period reached a record \$1.3 million, with billable samples up 78% from the prior-year period. We also managed our operating expenses, which declined as a percentage of sales, a trend that we expect to continue in 2017. Given these advancements and our plans to begin reporting sales on an accrual basis later this year, we believe that we remain on track to achieve our goal of becoming gross margin-positive in the second half of 2017.”

Mr. Nall continued, “In 2016, we achieved a more than five-fold increase in revenues over the prior year, and we strengthened our foundation for future growth with accomplishments such as introducing our PD-L1 protein expression assay for immuno-oncology applications and expanding our in-network coverage with major health plans to support reimbursement for our tests.

“We plan to further build on our position as a leader in liquid biopsy during 2017 by continuing to execute on our key initiatives aimed at increasing physician adoption of our Target Selector™ liquid biopsy platform,” concluded Mr. Nall. “Among these are our plans to introduce new actionable biomarker tests, provide additional clinical validation for our assays, expand the distribution of our tests through potential strategic partnerships, and enter into additional direct contracts with major health insurance plans.”

Review of 2016 and Recent Accomplishments

Corporate

- Completed two equity offerings in 2016 raising an aggregate of approximately \$15 million in gross proceeds.
- Increased our cash position since December 31, 2016 by approximately \$4.6 million as a result of the exercise of warrants from our October 2016 financing.
- Named Timothy Kennedy as Chief Financial Officer and Senior Vice President of Finance and Operations, and appointed David Moskowitz as Vice President, Strategy and Corporate Communications.

Commercial Biomarker Launches

- Expanded into immuno-oncology with the launch of our PD-L1 protein expression test to be among the first to commercialize a CLIA-validated, blood-based test for detection of this protein marker.
- Launched an androgen receptor (AR) test marking our expansion into prostate cancer and increasing our breast cancer offering into a subgroup of patients with triple negative breast cancer.
- Launched our RET oncogene fusion test to provide important information for therapeutic options for a subgroup of patients with non-small cell lung cancer.

Healthcare Payer Agreements

- Expanded managed care contracts with six new agreements, including Blue Cross Blue Shield of Texas and a group-purchasing agreement with a large, national health plan association.
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Collaborations

- Announced a Columbia University Medical Center-sponsored clinical study for our Target Selector™ platform using cerebrospinal fluid to rapidly and accurately diagnose brain metastases in breast cancer patients. The study is aimed at demonstrating the versatility of our platform in biofluids other than blood in order to address a true unmet clinical need.
- Announced a collaboration with MedStar Georgetown University Hospital to evaluate resistance biomarkers in patients diagnosed with non-small cell lung cancer being treated with EGFR inhibitors or chemotherapy.
- Signed a master services agreement with a major biopharmaceutical company to develop targeted liquid biopsy tests for multiple tumor types and molecular targets.
- Entered into a collaboration with renowned clinical investigator Shilpa Gupta, M.D., at Masonic Cancer Center, University of Minnesota, to study the clinical utility of liquid biopsy testing in bladder, testicular, and prostate cancers.
- Formed a Clinical Advisory Board of renowned oncologists to provide guidance on expanding our physician customer base and supporting usage of our liquid biopsy tests.

Industry Conferences and Study Results

- Presented study results providing robust analytical validation for our PD-L1 liquid biopsy test at the IASLC World Conference on Lung Cancer in collaboration with Dr. David Rimm of Yale University School of Medicine, a renowned PD-L1 diagnostics thought leader.
- Announced the presentation of study results demonstrating that our Target Selector™ platform delivered 90% concordance and the capability to rapidly detect EGFR, ALK, BRAF and ROS1 alterations in non-small cell lung cancer patients at the European Society for Medical Oncology (ESMO) Congress. Study collaborators were AstraZeneca and the National Cancer Institute in Mexico City.
- Announced the presentation of two abstracts supporting the use of our Target Selector™ platform for highly sensitive real-time monitoring and potential early identification of biomarkers at the American Society of Clinical Oncology (ASCO) conference.
- Reported results from a collaborative study with the Sarah Cannon Research Institute demonstrating high concordance of our Target-Selector™ platform versus tissue biopsy, and the ability to monitor key biomarkers in metastatic breast cancer in real time, at the San Antonio Breast Cancer Symposium.

Patents

- Awarded a U.S. patent covering the use of a novel stain in the detection of rare cells such as CTCs from blood and other biological fluids.
- Granted Japanese patent covering microchannel and antibody capture.
- Expanded patent protection in China to cover the use of a novel staining method in the detection of rare cells such as CTCs from blood and other biological fluids.
- Awarded patent in Australia for the use of antibodies in capturing cells in microchannels, including uses for CTCs and other rare cells.

International Marketing Agreements

- Entered into distribution agreements to market our portfolio of liquid biopsy tests in Canada with Teneovita Medical, in Israel with Progenetics, and in the Philippines with the Harle Group.
- Signed agreement with Quest Diagnostics Mexico to market proprietary liquid biopsy tests to detect EGFR mutations associated with lung cancer.

Fourth Quarter Financial Results

We accessioned 1,101 billable samples in the fourth quarter of 2016, a 78% increase from 618 billable samples accessioned during the fourth quarter of 2015. When samples from research, assay validations, and other non-billable sources are included, total samples were 1,175 during the fourth quarter of 2016, up 77% from 663 total samples for the fourth quarter of 2015.

Revenues for the fourth quarter of 2016 increased to \$1.3 million from \$218,000 for the fourth quarter of 2015. The current period included \$1.2 million in commercial test revenues and \$70,000 in development services test revenues.

Revenues from commercial samples are recognized on a cash basis, or when payment is collected. As a result, some collections may extend beyond the end of the quarter in which the samples were accessioned.

Cost of revenues of \$1.9 million for the fourth quarter of 2016 compares with \$1.3 million for the fourth quarter of 2015, with the increase primarily attributable to higher commercial test volumes. As test volumes continue to increase, we expect to leverage our fixed and semi-variable costs, reducing costs per patient sample, and improving margins.

Research and development expenses of \$668,000 for the fourth quarter of 2016 declined from \$784,000 for the fourth quarter of 2015, due to less consumption of materials and fewer lab costs associated with research and development activities.

General and administrative expenses for the fourth quarter of 2016 increased to \$1.6 million from \$1.4 million for the fourth quarter of 2015, primarily due to personnel costs associated with the expansion of our in-house billing and investor relation functions, as well as higher outsourced third-party billing fees resulting from greater cash collections.

Sales and marketing expenses of approximately \$1.2 million in the fourth quarter of 2016 were essentially flat from the same period last year, despite higher accession volumes.

Net loss for the fourth quarter of 2016 was \$4.2 million, or \$0.27 per share based on 15.6 million weighted-average shares outstanding. This compares to a net loss for the fourth quarter of 2015 of \$4.6 million, or \$0.73 per share based on 6.3 million weighted-average shares outstanding. The decrease in net loss was primarily due to growth in sample volume and higher collections from third-party insurers, partially offset by increased expenses to grow the business and the timing impact of revenue recognized when cash is collected, versus the recognition of expenses when samples are received and tested.

Full Year 2016 Financial Results

We accessioned 4,211 billable assays in 2016, an increase of 131% from 1,824 during 2015. Revenues in 2016 increased to \$3.2 million, up 428% from \$610,000 in the prior year.

Total costs and expenses were \$21.2 million in 2016, up from \$17.0 million for 2015, with the increase attributable primarily to cost of revenues due to higher commercial assay volume, as well as increased sales and marketing and general and administrative expenses to support the expanded commercial activities.

Net loss for 2016 was \$18.4 million, or \$1.92 per share based on 9.6 million weighted-average shares outstanding. This compares with a net loss of \$16.9 million for the same period in 2015, or \$3.07 per share based on 5.5 million weighted-average shares outstanding.

We reported cash and cash equivalents of \$4.6 million as of December 31, 2016. This compares with \$8.8 million as of December 31, 2015. In 2017 to date, we have received an additional \$4.6 million in proceeds related to warrant exercises from our October 2016 financing.

Conference Call and Webcast

Biocept will hold a conference call today at 4:30 pm 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 webcast will be available for 90 days.

A replay of the call will be available for 48 hours following the conclusion of the call 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 10101325.

About Biocept

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company leverages its proprietary liquid biopsy technology to provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer. Biocept's patented Target Selector™ liquid biopsy technology platform captures and analyzes tumor-associated molecular markers in both circulating tumor cells (CTCs) and in circulating tumor DNA (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 improve the outcomes of cancer patients, our ability to reduce our operating expenses and improve margins, our ability to become contribution margin-positive during 2017, our plans to begin reporting sales on an accrual basis later this year, our ability to grow our commercial test volume and adoption, our ability to pursue value-creating initiatives, and our ability to build on our commercial leadership position in the liquid biopsy field, 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 www.sec.gov.

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Biocept, Inc.
CONDENSED BALANCE SHEETS

	December 31,	December 31,
	2015	2016
		(Unaudited)
<u>ASSETS</u>		
Cash and cash equivalents	\$ 8,821,329	\$ 4,609,332
Accounts receivable	34,200	128,969
Inventories, net	349,271	549,045
Prepaid expenses and other current assets	435,938	484,649
TOTAL CURRENT ASSETS	9,640,738	5,771,995
FIXED ASSETS, NET	946,180	1,806,331
TOTAL ASSETS	\$ 10,586,918	\$ 7,578,326
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES	\$ 3,340,788	\$ 4,393,552
NON-CURRENT LIABILITIES, NET	3,553,395	2,526,113
TOTAL LIABILITIES	6,894,183	6,919,665
SHAREHOLDERS' EQUITY	3,692,735	658,661
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 10,586,918	\$ 7,578,326

Biocept, Inc.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended December 31,		For the year ended December 31,	
	2015	2016	2015	2016
	(Unaudited)	(Unaudited)		(Unaudited)
REVENUES	\$ 218,283	\$ 1,291,587	\$ 609,909	\$ 3,223,096
COSTS AND EXPENSES				
Cost of revenues	1,275,691	1,899,462	4,596,158	6,920,111
Research and development	784,379	668,399	2,857,770	2,713,367
General and administrative	1,404,515	1,636,994	5,686,398	6,560,425
Sales and marketing	1,264,168	1,179,167	3,880,386	5,054,230
Total costs and expenses	4,728,753	5,384,022	17,020,712	21,248,133
LOSS FROM OPERATIONS	(4,510,470)	(4,092,435)	(16,410,803)	(18,025,037)
INTEREST AND OTHER INCOME/(EXPENSE),				
NET	(106,900)	(94,439)	(537,115)	(372,232)
LOSS BEFORE INCOME TAXES	(4,617,370)	(4,186,874)	(16,947,918)	(18,397,269)
INCOME TAXES	(130)	—	(1,608)	(2,053)
NET LOSS & COMPREHENSIVE LOSS	\$ (4,617,500)	\$ (4,186,874)	\$ (16,949,526)	\$ (18,399,322)
NET LOSS PER SHARE				
- Basic	\$ (0.73)	\$ (0.27)	\$ (3.07)	\$ (1.92)
- Diluted	\$ (0.73)	\$ (0.27)	\$ (3.07)	\$ (1.92)
WEIGHTED AVG NUMBER OF SHARES				
OUTSTANDING				
- Basic	6,307,316	15,620,049	5,512,989	9,578,285
- Diluted	6,307,316	15,620,049	5,512,989	9,578,285