

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): August 10, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2017, we issued a press release announcing our financial results for the three and six-months ended June 30, 2017. 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 August 10, 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: August 10, 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 Second Quarter 2017 Financial Results

- Reported revenues of \$1.3 million in 2Q 2017 vs. \$663,000 in 2Q 2016, up 93%, or 64% excluding the impact of conversion to accrual-based revenue recognition
- Launch of “AND” campaign supports growth in test volume both sequentially and year-over-year
- New provider agreements with both Scripps Health Plan and MediNcrease expand patient access to Biocept’s proprietary liquid biopsy test platform
- Secures \$2.2 million investment from Ally Bridge LB Healthcare Master Fund
- Evaluating strategic opportunities in China with Ally Bridge’s Chinese affiliate

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

SAN DIEGO (August 10, 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 and six-months ended June 30, 2017, and provides an update on its business progress.

“Our positive 2Q 2017 financial results reflect the Company’s focus on increasing sales force productivity, refreshing our marketing message, and improving collections from third party health plans to accelerate growth of our revenue and test volume,” said Michael Nall, President and CEO of Biocept. “In early June at the American Society of Clinical Oncology annual meeting, we launched the ‘AND’ marketing campaign which highlights the advantages of combining liquid biopsy and tissue biopsy for patients with metastatic non-small cell lung cancer (NSCLC). To date, we’ve received a positive reception from physicians to this campaign, given the potential to qualify more cancer patients for targeted therapy in the first-line setting using Biocept’s liquid biopsy platform.”

“We also made progress on several other initiatives in the recent period including the launch of our newest liquid biopsy test for progesterone receptor, entry into two health plan contracts with Scripps and MediNcrease, and the issuance of broad patents on our core Target Selector™ technology in both the U.S. and Japan. Additionally, we formalized our process for pursuing strategic partnering opportunities in the U.S. and abroad.”

“Earlier today, we announced a \$2.2 million investment from Ally Bridge LB Healthcare Master Fund, a highly respected institutional investor focused on the healthcare sector. The additional capital from Ally Bridge strengthens our balance sheet and is intended to enable us to continue to execute on our plans to grow the business and evaluate opportunities to leverage our cost infrastructure and extend our cash runway. We are also very excited about working with Ally Bridge to evaluate strategic opportunities in China.

Review of Second Quarter 2017 and Recent Accomplishments

Corporate Developments

- Announced \$2.2 million private financing with Ally Bridge LB Healthcare Master Fund. Biocept is also evaluating strategic opportunities with Ally Bridge regarding the Company’s liquid biopsy platform in China.
- Named to the Russell Microcap® Index, which is used by investment managers as a benchmark for active investment strategies.
- Launched the “AND” marketing campaign highlighting the potential benefits of using both liquid biopsy and tissue biopsy to improve the convenience, cost, and time to identify clinically actionable biomarkers in patients with NSCLC.

Collaborations

- Selected by the Addario Lung Cancer Medical Institute (ALCMI) to participate as a liquid biopsy testing provider in the landmark ALCMI-009 Liquid Biopsy trial, a 400-patient, multicenter, well-controlled,

prospective trial to demonstrate the clinical utility of liquid biopsy for use in detecting and assessing clinically actionable biomarkers from the blood of patients with NSCLC.

- Announced a multiphase agreement granting Oregon Health Sciences University (OHSU) exclusive rights to offer Biocept's Target Selector™ liquid biopsy testing services throughout the state of Oregon.

Patents

- Granted U.S. patent with broad claims for antibody capture of targets of interest on any solid surface including circulating tumor cells (CTCs) and other materials shed by solid tumors into blood.
- Awarded patent in Japan for the use of antibodies to capture any target of interest from any sample type, including CTCs, sub-cellular vesicles and exosomes.

Commercial Biomarker Launch

- Expanded commercially available biomarkers for breast cancer with the launch of a liquid biopsy test for progesterone receptor (PR).

Healthcare Payer Agreements

- Executed preferred provider agreements with both Scripps Health Plan and MediNcrease, expanding in-network access to Biocept's liquid biopsy testing.

Clinical Data Presentation

- Three scientific and medical abstracts regarding the Company's Target Selector™ liquid biopsy platform featured at the 2017 ASCO Annual Meeting.

Second Quarter Financial Results

Revenues for the second quarter of 2017 increased 93% to \$1.3 million from \$663,000 in the second quarter of 2016, and included \$1.2 million in commercial test revenues and \$84,000 in development services test revenues. Of the \$1.3 million of revenues recognized during the second quarter of 2017, \$1.1 million related to revenues recognized on an accrual basis, while \$0.2 million related to revenues recognized upon the receipt of cash. During the first quarter of 2017, the Company converted from cash-based revenue recognition for its commercial revenues, to accrual-based revenue recognition. As a result of the change to accrual accounting, the Company recognized total nonrecurring revenue of \$135,000 during the second quarter of 2017 for cases delivered on or prior to December 31, 2016, and the incremental revenue as a result of the change to accrual accounting for commercial cases was \$191,000.

Biocept accessioned 1,225 billable samples during the second quarter of 2017, a 9% increase from 1,126 billable samples accessioned during the second quarter of 2016. Total accessions, which also includes samples from research activities, assay validations, and other non-billable sources, were 1,405 for the second quarter of 2017, up 16% from 1,212 total samples for the second quarter of 2016.

Cost of revenues for the second quarter of 2017 was \$2.4 million, compared with \$1.7 million for the second quarter of 2016, with the increase primarily attributable to higher commercial test volumes and an increase in laboratory capacity to service anticipated higher sample volume resulting from the Company's sales force expansion. As test volumes continue to increase, the Company expects to leverage its fixed and semi-variable costs, reducing costs per sample and improving margins.

Research and development (R&D) expenses for the second quarter of 2017 were \$842,000 compared with \$716,000 for the prior-year period, with the increase due to greater consumption of materials and higher costs associated with research and development activities.

General and administrative (G&A) expenses for the second quarter of 2017 were \$1.8 million compared with \$1.5 million for the second quarter of 2016, primarily due to higher personnel costs associated with the expansion of the Company's in-house billing and investor relations functions.

Sales and marketing expenses for the second quarter of 2017 were \$1.7 million, versus \$1.3 million for the second quarter of 2016, due to sale force expansion.

The net loss for the second quarter of 2017 was \$5.7 million, or \$0.21 per share on 26.8 million weighted-average shares outstanding. This compares with a net loss for the second quarter of 2016 of \$4.6 million, or \$0.60 per share on 7.7 million weighted-average shares outstanding.

Six Month Financial Results

Revenues for the first six months of 2017 increased more than three-fold to \$3.0 million from \$884,000 in the first six months of 2016, and included \$2.8 million in commercial test revenues and \$144,000 in development services test revenues. Of the \$3.0 million of revenues recognized during the first six months of 2017, \$1.9 million related to revenues recognized on an accrual basis, while \$1.1 million related to revenues recognized upon the receipt of cash. During the first quarter of 2017, the Company converted from cash-based revenue recognition for its commercial revenues, to accrual-based revenue recognition. As a result of the change to accrual accounting, the Company recognized total nonrecurring revenue of \$1,012,000 during the first six months of 2017 for cases delivered on or prior to December 31, 2016, and the incremental revenue as a result of the change to accrual accounting for commercial cases was \$917,000.

Biocept accessioned 2,332 billable samples during the first six months of 2017, a 21% increase from 1,927 billable samples accessioned during the first six months of 2016. Total accessions, which also includes samples from research activities, assay validations and other non-billable sources, were 2,651 for the first six months of 2017, up 25% from 2,114 total samples for the first six months of 2016.

Cost of revenues for the first six months of 2017 was \$4.5 million, compared with \$3.1 million for the first six months of 2016, with the increase primarily attributable to higher commercial test volumes and an increase in laboratory capacity to service anticipated higher sample volume resulting from the Company's sales force expansion. As test volumes continue to increase, the Company expects to leverage its fixed and semi-variable costs, reducing costs per sample and improving margins.

R&D expenses for the first six months of 2017 were \$1.6 million compared with \$1.4 million for the prior-year period, with the increase due to greater consumption of materials and higher costs associated with research and development activities.

G&A expenses for the first six months of 2017 were \$3.7 million compared with \$3.0 million for the first six months of 2016, primarily due to higher personnel costs associated with the expansion of the Company's in-house billing and investor relations functions, as well as higher consulting and outside service provider costs associated with increased commercial activities and corporate strategy initiatives.

Sales and marketing expenses for the first six months of 2017 were \$3.0 million, versus \$2.6 million for the first six months of 2016, due to sale force expansion.

The net loss for the first six months of 2017 was \$10.1 million, or \$0.42 per share on 23.9 million weighted-average shares outstanding. This compares with a net loss for the first six months of 2016 of \$9.5 million, or \$1.33 per share on 7.1 million weighted-average shares outstanding.

Cash and cash equivalents were \$10.0 million as of June 30, 2017, compared with \$4.6 million as of December 31, 2016. Earlier today, Biocept announced that it had entered into a common stock and warrant purchase agreement with Ally Bridge LB Healthcare Master Fund to purchase Biocept common stock and warrants for an aggregate gross purchase amount of \$2.2 million.

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 1011122.

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 provide physicians with clinically actionable information to improve the outcomes of cancer patients, our ability to improve collections and accelerate the growth of our revenue and test volume, our ability to pursue strategic partnering opportunities in the U.S. and abroad, the proceeds from our financing with Ally Bridge LB Healthcare Master Fund Limited, our ability to execute on our plans to grow our business, our ability to consummate a strategic transaction with Ally Bridge to leverage our liquid biopsy platform in China, and our ability to leverage our fixed and semi-variable costs to improve margins, 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, as well as risks related to the fact that discussions with Ally Bridge to evaluate potential strategic opportunities in China are preliminary and there is no obligation on either party to continue discussions or to enter into a binding agreement. Until such time, if ever, that we enter into a binding agreement with Ally Bridge for a strategic transaction, there can be no guarantee that we will be able to consummate a strategic transaction to leverage our liquid biopsy platform in China. 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.

Investor Contact:

LHA

Jody Cain
Jcain@lhai.com
310-691-7100

Media Contact:

Trevelino/Keller
Colleen Murphy
cmurphy@trevelinokeller.com
404-214-0722, Ext. 109

Biocept, Inc.
CONDENSED BALANCE SHEETS

	<u>December 31,</u> <u>2016</u>	<u>June 30,</u> <u>2017</u>
		(unaudited)
<u>ASSETS</u>		
Cash	\$ 4,609,332	\$ 10,000,155
Accounts receivable, net	128,969	994,746
Inventories, net	549,045	631,210
Prepaid expenses and other current assets	484,649	624,827
TOTAL CURRENT ASSETS	<u>5,771,995</u>	<u>12,250,938</u>
FIXED ASSETS, NET	1,806,331	2,402,255
TOTAL ASSETS	<u>\$ 7,578,326</u>	<u>\$ 14,653,193</u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES, NET	\$ 4,393,552	\$ 5,749,416
NON-CURRENT LIABILITIES, NET	<u>2,526,113</u>	<u>1,561,520</u>
TOTAL LIABILITIES	6,919,665	7,310,936
SHAREHOLDERS' EQUITY	<u>658,661</u>	<u>7,342,257</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 7,578,326</u>	<u>\$ 14,653,193</u>

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

	For the three months ended June 30,		For the six months ended June 30,	
	2016	2017	2016	2017
NET REVENUES	\$ 662,860	\$ 1,278,961	\$ 884,229	\$ 2,962,026
COSTS AND EXPENSES				
Cost of revenues	1,669,571	2,368,705	3,144,361	4,498,159
Research and development	716,279	841,991	1,444,355	1,599,249
General and administrative	1,517,664	1,798,026	3,004,888	3,704,661
Sales and marketing	1,291,709	1,746,867	2,596,608	3,025,178
Total costs and expenses	5,195,223	6,755,589	10,190,212	12,827,247
LOSS FROM OPERATIONS	(4,532,363)	(5,476,628)	(9,305,983)	(9,865,221)
INTEREST AND OTHER INCOME/(EXPENSE),				
NET	(61,308)	(214,377)	(161,336)	(258,491)
LOSS BEFORE INCOME TAXES	(4,593,671)	(5,691,005)	(9,467,319)	(10,123,712)
INCOME TAXES	(503)	(2,146)	(2,053)	(2,146)
NET LOSS AND COMPREHENSIVE LOSS	\$ (4,594,174)	\$ (5,693,151)	\$ (9,469,372)	\$ (10,125,858)
NET LOSS PER SHARE				
- Basic	\$ (0.60)	\$ (0.21)	\$ (1.33)	\$ (0.42)
- Diluted	\$ (0.60)	\$ (0.21)	\$ (1.33)	\$ (0.42)
WEIGHTED AVG NUMBER OF SHARES				
OUTSTANDING				
- Basic	7,702,286	26,778,549	7,134,639	23,889,888
- Diluted	7,702,286	26,778,549	7,134,639	23,889,888