## 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): November 9, 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))

Dere-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  $\boxtimes$ 

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 November 9, 2017, we issued a press release announcing our financial results for the three and nine-months ended September 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 November 9, 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: November 9, 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 Third Quarter 2017 Financial Results**

- Despite the impact from natural disasters and fewer sales days, revenues were up 6% and 111% in 3Q 2017 and year to date, respectively, versus the prior year periods inclusive of the impact of conversion to accrual based revenue recognition
- Distribution agreement signed with VWR to distribute Biocept's patented blood collection tube
- Co-Marketing agreement signed with Miraca Life Sciences
- Pathology Program initiative underway to expand adoption of Biocept's Target Selector™ platform to more community pathologists, oncologists and hematologists
- Newly launched liquid biopsy tests complete the complement of biomarker testing for breast cancer, metastatic melanoma and colorectal cancer under NCCN<sup>®</sup> Guidelines and bring the total number of commercially available liquid biopsy tests to 15
  - Company to host conference call at 4:30 p.m. Eastern time today

**SAN DIEGO (November 9, 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 nine months ended September 30, 2017, and provides an update on its business progress.

"This has been a productive period in developing new distribution channels, launching key biomarker tests, and initiating an important clinical study all aimed at supporting further physician adoption of our Target Selector<sup>™</sup> liquid biopsy platform," said Michael Nall, President and CEO of Biocept. "By signing the distribution agreement with VWR and launching our Pathology Program strategy, we are executing on key steps towards our strategy to move to the distribution of our patented technologies while also continuing to be a leader in the liquid biopsy services space."

"Our Pathology Program initiative is a first-of-its-kind strategy in liquid biopsy focused on community pathologists, the physicians who determine patient diagnosis. Pathologists have strong relationships with medical oncologists and other physicians who refer specimens to them, and are the first to know when tissue is limited or inadequate from a traditional surgical biopsy. This novel program allows us to expand our relationships with hospital systems across the U.S. while improving continuity of care for these patients by bringing more stakeholders into the liquid biopsy value chain," he added. "We also entered a co-marketing agreement with Miraca Life Sciences, a leading U.S. diagnostics and services provider, to broaden the distribution of our liquid biopsy tests to community-based oncologists and hematologists. This arrangement will give us broader coverage in order to drive adoption of our industry-leading testing solutions. In addition, we entered into a research agreement with the University of Texas Southwestern Medical Center to study ALK alterations in non-small cell lung cancer. Patients who have an ALK translocation have been shown to benefit from targeted therapy."

#### **Review of Third Quarter 2017 and Recent Accomplishments**

#### Distribution Agreements

- Launched the first and only initiative in liquid biopsy to enable community pathologists to report molecular biomarker information using innovative liquid biopsy technology for their patients diagnosed with cancer.
- Entered into an agreement with leading diagnostics laboratory and service provider Miraca Life Sciences to market Target Selector™ liquid biopsy tests and services to community-based oncologists and hematologists across the U.S.
- Entered into an exclusive global agreement (excluding China) with global laboratory product supplier VWR International, LLC to distribute Biocept's proprietary blood collection tubes that preserve circulating tumor DNA (ctDNA) for up to 8 days and circulating tumor cells (CTCs) for up to 4 days at room temperature, thereby enabling worldwide shipment of liquid biopsy samples.

Clinical Development

• Initiated a clinical study with the University of Texas Southwestern Medical Center to profile and monitor non-small cell lung cancer patients with ALK rearrangements using our Target Selector<sup>™</sup> liquid biopsy test.

#### Commercial Biomarker Launch

- Announced the commercial availability of the Company's assay for mutations of the NRAS oncogene associated with multiple cancer types including metastatic melanoma, colorectal and lung cancers, increasing the number of CLIA-certified liquid biopsy tests to 15.
- Increased the number of commercially available biomarkers for breast cancer with the launch of a liquid biopsy test for progesterone receptor (PR), which completes our menu of assays for all NCCN Guideline®-based biomarkers pertinent to the care of patients with breast cancer.

#### Healthcare Payer Agreements

• Executed a preferred provider agreement with Scripps Health Plan, expanding in-network access to Biocept's liquid biopsy testing.

#### Corporate Developments

Named renowned lung cancer expert Fred R. Hirsch, MD, PhD, Professor of Medicine and Pathology at the University of Colorado Cancer Center, to Biocept's Clinical Advisory Board.

#### **Third Quarter Financial Results**

Revenues for the third quarter of 2017 increased 6% to \$1.1 million, from \$1.0 million for the third quarter of 2016, and included \$1.0 million in commercial test revenues and \$67,000 in development services test revenues. These results reflect the impact on sales and volume from the hurricanes in Texas and Florida, as well as the earthquake in Mexico City. In addition, there were 2 less sales days in the third quarter of 2017 as compared to the third quarter of 2016. We believe these factors negatively impacted our reported volume in the third quarter of 2017 by approximately 15 to 20%. Of the \$1.1 million of revenues recognized during the third quarter of 2017, \$0.9 million related to revenues recognized on an accrual basis and \$102,000 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. The Company recognized incremental revenue in the third quarter of \$125,000 as a result of the change to accrual accounting for commercial cases.

Biocept accessioned 1,343 total samples in the third quarter of 2017, up 7% from the 1,251 total samples in the third quarter of 2016. Total accessions include billable samples and samples from research activities, assay validations and other non-billable sources. The Company accessioned 1,203 billable samples in the third quarter of 2017, a 2% increase from the 1,183 billable samples accessioned during the third quarter of 2016.

Cost of revenues for the third quarter of 2017 was \$2.5 million, compared with \$1.9 million for the third quarter of 2016, with the increase primarily attributable to an increase in laboratory capacity to service anticipated higher sample volume resulting from the Company's sales force expansion, pathology partnership initiative, and investments in upgrading its laboratory information system, equipment, and facility. As test volumes continue to increase, the Company expects to leverage its fixed and semi-variable costs, reducing costs per sample and improving gross margins.

Research and development (R&D) expenses for the third quarter of 2017 were \$857,000 compared with \$601,000 for the prior-year period, with the increase due to higher headcount, greater consumption of materials and higher costs associated with research and development activities.

General and administrative (G&A) expenses for the third quarter of 2017 were \$1.8 million compared with \$1.9 million for the third quarter of 2016, with the decrease primarily due to lower third-party billing provider costs resulting from bringing the Company's billing function in-house, lower stock-based compensation expense and lower patent costs.

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

The net loss for the third quarter of 2017 was \$5.8 million, or \$0.20 per share on 29.6 million weighted-average shares outstanding. This compares with a net loss for the third quarter of 2016 of \$4.7 million, or \$0.57 per share on 8.4 million weighted-average shares outstanding.

#### **Nine Month Financial Results**

Revenues for the first nine months of 2017 more than doubled to \$4.1 million from \$1.9 million for the first nine months of 2016, and included \$3.9 million in commercial test revenues and \$212,000 in development services test revenues. Of the \$4.1 million of revenues recognized during the first nine months of 2017, \$2.9 million related to revenues recognized on an accrual basis and \$1.2 million related to revenues recognized upon the receipt of cash. As a result of the change to accrual accounting during the first quarter of 2017, the Company recognized total nonrecurring revenue of \$839,000 during the first nine 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 \$1.0 million.

Biocept accessioned 3,994 total samples during the first nine months of 2017, up 19% from the 3,365 total samples for the first nine months of 2016. Total accessions include billable samples and samples from research activities, assay validations and other non-billable sources. The Company accessioned 3,535 billable samples during the first nine months of 2017, a 14% increase from the 3,110 billable samples accessioned during the first nine months of 2016.

Cost of revenues for the first nine months of 2017 was \$7.0 million, compared with \$5.0 million for the first nine 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, pathology partnership initiative, and investments in upgrading its laboratory information system, equipment, and facility.

R&D expenses for the nine months ended September 30, 2017 were \$2.5 million compared with \$2.0 million for the prior-year period, with the increase due to higher headcount and higher costs associated with research and development activities.

G&A expenses for the first nine months of 2017 were \$5.5 million compared with \$4.9 million for the first nine months of 2016, primarily due to higher personnel costs associated with the expansion of the Company's in-house billing function, 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 nine months of 2017 were \$4.7 million, versus \$3.9 million for the first nine months of 2016, due to salesforce expansion and higher marketing costs.

The net loss for the first nine months of 2017 was \$15.9 million, or \$0.62 per share on 25.8 million weighted-average shares outstanding. This compares with a net loss for the first nine months of 2016 of \$14.2 million, or \$1.88 per share on 7.5 million weighted-average shares outstanding.

Cash and cash equivalents were \$5.9 million as of September 30, 2017, compared with \$4.6 million as of December 31, 2016.

#### **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 <u>http://ir.biocept.com/events.cfm</u>. 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 10113804.

#### **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<sup>TM</sup> 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 increase physician adoption of our liquid biopsy platform, our ability to move to the distribution of our patented technologies, our ability to expand relationships with hospital systems across the U.S., our ability to broaden the distribution of our liquid biopsy tests, 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. 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

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## <u>Biocept, Inc.</u> CONDENSED BALANCE SHEETS

	December 31,			September 30,	
	2016			2017	
ASSETS				(unaudited)	
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Cash	\$	4,609,332	\$	5,879,025	
Accounts receivable, net		128,969		1,133,372	
Inventories, net		549,045		775,106	
Prepaid expenses and other current assets		484,649		412,916	
TOTAL CURRENT ASSETS		5,771,995		8,200,419	
FIXED ASSETS, NET		1,806,331		2,919,796	
TOTAL ASSETS	\$	7,578,326	\$	11,120,215	
LIABILITIES AND SHAREHOLDERS' EQUITY					
CURRENT LIABILITIES, NET	\$	4,393,552	\$	5,838,197	
NON-CURRENT LIABILITIES, NET		2,526,113		1,255,939	
TOTAL LIABILITIES		6,919,665		7,094,136	
SHAREHOLDERS' EQUITY		658,661		4,026,079	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	7,578,326	\$	11,120,215	

## <u>Biocept, Inc.</u> CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

	For the three months ended September 30,			For the nine months ended September 30,				
		2016		2017		2016		2017
NET REVENUES	\$	1,047,280	\$	1,111,411	\$	1,931,509	\$	4,073,437
COSTS AND EXPENSES								
Cost of revenues		1,876,288		2,487,054		5,020,649		6,985,213
Research and development		600,613		856,698		2,044,968		2,455,947
General and administrative		1,918,543		1,834,771		4,923,431		5,539,432
Sales and marketing		1,278,455		1,675,852		3,875,063		4,701,030
Total costs and expenses		5,673,899		6,854,375		15,864,111		19,681,622
LOSS FROM OPERATIONS		(4,626,619)		(5,742,964)		(13,932,602)		(15,608,185)
INTEREST AND OTHER INCOME/(EXPENSE)	),							
NET		(116,457)		(75,465)		(277,793)		(333,956)
LOSS BEFORE INCOME TAXES		(4,743,076)		(5,818,429)		(14,210,395)		(15,942,141)
INCOME TAXES		—		(2,877)		(2,053)		(5,023)
NET LOSS AND COMPREHENSIVE LOSS	\$	(4,743,076)	\$	(5,821,306)	\$	(14,212,448)	\$	(15,947,164)
NET LOSS PER SHARE								
- Basic	\$	(0.57)	\$	(0.20)	\$	(1.88)	\$	(0.62)
- Diluted	\$	(0.57)	\$	(0.20)	\$	(1.88)	\$	(0.62)
WEIGHTED AVG NUMBER OF SHARES					_			
OUTSTANDING								
- Basic		8,370,691		29,605,953		7,549,663		25,816,181
- Diluted	_	8,370,691	_	29,605,953		7,549,663		25,816,181