# 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 13, 2019

# 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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$.0001 per share	BIOC	The Nasdag Stock Market LLC

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

#### Item 2.02 Results of Operations and Financial Condition.

On November 13, 2019, we issued a press release announcing our financial results for the three and nine months ended September 30, 2019. 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 13, 2019.

### SIGNATURES

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.

BIOCEPT, INC.

Dated: November 13, 2019

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 2019 Financial Results**

- Revenues reached a record \$1.5 million, up 101% over the third quarter of 2018 and up 28% over the second quarter of 2019
- The number of commercial samples received increased 66% over the third quarter of 2018 and 12% over the second quarter of 2019
- Cost of revenue reduced 23% on a per accession basis versus the third quarter of 2018
- Revenues for the first nine-month of 2019 increased 57% and the number of commercial samples received increased 32% over the first nine months of 2018
- Conference call begins at 4:30 p.m. Eastern time today

**SAN DIEGO (November 13, 2019)** – <u>Biocept, Inc.</u> (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, 2019, and provides an update on its business progress.

"We continued to deliver strong growth during the third quarter of 2019 with revenues reaching a record \$1.5 million, up 101% over the same period in the prior year and up 28% over the second quarter of this year," said Michael Nall, President and CEO of Biocept. "Our momentum was driven by a 66% year-over-year increase in the number of commercial samples received, as we focus on segments of the liquid biopsy market where our Target Selector<sup>TM</sup> technologies and testing platform can help the most patients, namely patients with lung, prostate and breast cancers. In addition, we continue to work to control expenses, which has moved us closer to gross margin positive. We are focused on continued growth in commercial volume and improvement in gross margin percent through operational efficiencies.

"Testing for lung cancer continued to be among the largest contributors to commercial volume due to the difficulties in securing lung tissue samples from this patient population," he added. "We also continue to gain traction in the uro-oncology market where our blood-based testing is used by urologists to monitor patients with rising prostate-specific antigen (PSA) levels as well as in the post-surgery setting to identify patients at risk for cancer recurrence. We are seeing increasing reorders from the physicians and practices who began using our Target Selector<sup>TM</sup> products earlier this year, while establishing relationships with additional urologists and urology practice groups during the third quarter. We expect continued growth in this business segment.

"Our Target Selector<sup>TM</sup> testing for breast cancer was also a key contributor to commercial volume growth during the quarter. Clinicians treating patients with breast cancer are utilizing our blood-based assays for initial profiling of biomarkers to ensure that critical biomarkers are not missed with the original tissue biopsy as well as to re-profile patients who have cancer recurrence in order to determine the most appropriate treatment plan for each patient," Nall said.

**Review of Third Quarter and Recent Highlights** 

Commercial Agreements

Announced an agreement with Beacon Laboratory Benefit Solutions designating Biocept as a BeaconLBS® Lab-of-Choice. Beacon
Laboratory is a nationally recognized provider of laboratory benefit management technology solutions to U.S.-based health and managed
care companies. This designation increases patient access to Biocept's liquid biopsy testing platforms.

#### Regulatory Approval

• Obtained CE IVD Marks for the CEE-Sure® Blood Collection Tube and the CEE-Sure® Sample Collection Shipping Kit in Europe. These CE Marks confirm that Biocept's CEE-Sure® products, which are specifically designed to collect and transport blood and other liquid biopsy specimens, meet the requirements of the European In-Vitro Diagnostic Devices Directive. This allows Biocept to commercialize its tubes and collection/shipping kits throughout the European Union and other CE Mark geographies.

#### **Industry Conferences and Study Results**

- Announced the presentation of six posters at the 2019 Association for Molecular Pathology (AMP) Annual Meeting featuring clinical data highlighting Target Selector<sup>TM</sup> tests and kits. The content of these posters is expected to be published in a future issue of *The Journal of Molecular Diagnostics*.
- Presented data at the 2019 IASLC World Conference on Lung Cancer highlighting the ability of Biocept's circulating tumor DNA (ctDNA) assays to consistently detect actionable biomarkers from the blood of patients diagnosed with lung cancer at a mutant allele frequency as low as 0.01%. The poster featured clinical experience data from more than 1,400 blood samples drawn from patients diagnosed with non-small cell lung cancer, and collected and shipped using the Company's CEE-Sure® Blood Collection Tubes.

#### Peer-reviewed Journal Publications

• Announced publication of an article in the peer-reviewed journal *PLOS ONE* featuring analytical validation results demonstrating the ultrasensitive detection of Target Selector<sup>™</sup> testing for EGFR, BRAF and KRAS mutations in plasma ctDNA. These tests can be performed in the Company's CLIA laboratory with a commercial turnaround time of only three to four days.

#### Intellectual Property

- Awarded U.S., Canadian and European patents covering antibody and microchannel technology and enhanced detection of cancer
  cells. These new patents further expand Biocept's intellectual property estate for capturing and detecting rare cells of interest, including
  CTCs to aid in the management of patients with cancer.
- Granted a South Korean patent covering the Target Selector<sup>TM</sup> oncogene mutation enrichment and detection platform for proprietary Switch-Blocker technology that is core to Target Selector<sup>TM</sup> assays for molecular analysis using real-time PCR, Sanger sequencing and next-generation sequencing.
- Ended the period with 36 issued patents globally for Biocept's highly sensitive method of detecting cancer biomarkers.

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

Revenues for the third quarter of 2019 were \$1.5 million, a 101% increase from \$762,000 for the third quarter of 2018. Revenues for the third quarter of 2019 included \$1.4 million in commercial test revenue, \$40,000 in development services test revenue and \$60,000 in revenue for Target Selector<sup>TM</sup> RUO kits, which were commercially launched in early 2019, and CEE-Sure® blood collection tubes. Revenues for the third quarter of 2018 included \$698,000 in commercial test revenues and \$64,000 in development services test revenues.

Biocept accessioned 1,189 commercial samples during the third quarter of 2019, a 66% increase from the 717 commercial samples accessioned during the third quarter of 2018. The Company accessioned 1,332 billable samples in the third quarter of 2019, a 52% increase from 878 billable samples for the third quarter of 2018.

Cost of revenues for the third quarter of 2019 was \$2.8 million, compared with \$2.5 million for the third quarter of 2018. Cost of revenues for the third quarter of 2019 increased 14% while volume increased by nearly 50% as the Company continued to leverage its fixed costs.

Research and development (R&D) expenses for the third quarter of 2019 were \$1.2 million, compared with \$1.1 million for the third quarter of 2018, with the increase primarily due to an increase in materials used for developing and validating new assays. General and administrative (G&A) expenses for the third quarter of 2019 were \$1.7 million, a decrease from \$1.8 million during the third quarter of 2018 as the Company continued its cost-containment program. Sales and marketing (S&M) expenses for the third quarter of 2019 were \$1.5 million, compared with \$1.4 million for the third quarter of 2018, with the increase primarily attributed to commissions paid for higher volume and revenue.

The third quarter of 2018 included a non-cash deemed dividend of \$0.6 million for the repricing of adjustable warrants. There was no comparable charge in the third quarter of 2019.

The net loss attributable to common shareholders for the third quarter of 2019 was \$5.7 million, or \$0.25 per share on 23.0 million weighted-average shares outstanding. The net loss attributable to common shareholders for the third quarter of 2018 was \$6.7 million, or \$2.42 per share on 2.8 million weighted-average shares outstanding. The Company completed a 1-for-30 reverse stock split of its common stock in July 2018.

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

Revenues for the first nine months of 2019 were \$3.7 million, a 57% increase from \$2.4 million for the first nine months of 2018, and included \$3.5 million in commercial test revenues, \$130,000 in development services test revenues, and \$90,000 in revenues for Target Selector RUO kits and CEE-Sure® blood collection tubes.

Total costs and expenses for the first nine months of 2019 were \$21.2 million, and included cost of revenues of \$8.1 million, R&D expenses of \$3.5 million, G&A expenses of \$5.1 million and S&M expenses of \$4.5 million.

Other expense for the first nine months of 2019 of \$2.0 million consisted of non-cash warrant inducement expenses associated with recognizing the fair value of the inducement warrants issued in May 2019 of \$1.8 million and \$190,000 of interest expense. This compares with other expense of \$240,000 for the first nine months of 2018 related to interest expense. The nine months ended September 30, 2019 included a non-cash deemed dividend of \$0.1 million for the repricing of adjustable warrants, compared with a non-cash deemed dividend of \$0.6 million for the repricing of adjustable warrants during the nine months ended September 30, 2018.

The net loss attributable to common shareholders for the first nine months of 2019 was \$19.5 million, or \$1.10 per share on 17.8 million weighted-average shares outstanding. This compares with a net loss attributable to common shareholders for the first nine months of 2018 of \$19.2 million, or \$8.26 per share on 2.3 million weighted-average shares outstanding. The Company completed a 1-for-30 reverse stock split of its common stock in July 2018.

Biocept reported cash and cash equivalents as of September 30, 2019 of \$6.5 million, compared with \$3.4 million as of December 31, 2018. The increase was due to \$17.0 million in net proceeds from equity capital raises conducted in the first quarter of 2019, and \$4.9 million from the exercise of common stock warrants exercised year-to-date in 2019.

#### **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 <a href="http://ir.biocept.com/events.cfm">http://ir.biocept.com/events.cfm</a>. A replay of the webcast will be available for 90 days.

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 10135501.

#### **About Biocept**

Biocept, Inc. is a molecular diagnostics company with commercialized assays for lung, breast, gastric, colorectal and prostate cancers, and melanoma. The Company uses its proprietary liquid biopsy technology to provide physicians with information for treating and monitoring patients diagnosed with cancer. The Company'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 plasma (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 <a href="https://www.biocept.com">www.biocept.com</a>.

#### 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 grow our business and drive adoption of our products, and our expectation of continued growth in the uro-oncology business segment, 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, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019. 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.

Investor Contact: LHA Investor Relations Jody Cain Jcain@lhai.com (310) 691-7100

## BIOCEPT, INC. CONDENSED BALANCE SHEETS

	December 31,		September 30,		
		2018	2019		
				(unaudited)	
ASSETS					
Cash	\$	3,423,373	\$	6,539,444	
Accounts receivable, net		1,574,325		2,861,659	
Inventories, net		587,222		687,186	
Prepaid expenses and other current assets		425,961		497,121	
TOTAL CURRENT ASSETS		6,010,881	. <u></u>	10,585,410	
FIXED ASSETS, NET		2,739,422		1,325,255	
LEASE RIGHT-OF-USE ASSETS		_		2,610,249	
TOTAL ASSETS	\$	8,750,303	\$	14,520,914	
LIABILITIES AND SHAREHOLDERS' EQUITY			-		
CURRENT LIABILITIES, NET	\$	4,609,647	\$	5,783,213	
NON-CURRENT LIABILITIES, NET		1,098,137		1,032,243	
TOTAL LIABILITIES		5,707,784	_ <del></del>	6,815,456	
SHAREHOLDERS' EQUITY		3,042,519		7,705,458	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	8,750,303	\$	14,520,914	

# BIOCEPT, INC. CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

For the three months ended September 30,

For the nine months ended September 30

	2018 (unaudited)		2019 (unaudited)		2018 (unaudited)		_	2019
								(unaudited
NET REVENUES	\$	761,591	\$	1,529,262	\$	2,390,772	\$	3,
COSTS AND EXPENSES								,
Cost of revenues	\$	2,481,916	\$	2,832,735	\$	7,616,473	\$	8,
Research and development expenses		1,089,746		1,163,546		3,179,612		3,
General and administrative expenses		1,793,720		1,700,380		5,441,354		5,1
Sales and marketing expenses		1,404,192		1,462,335		4,473,908		4,
Total costs and expenses		6,769,574		7,158,996		20,711,347		21,
LOSS FROM OPERATIONS		(6,007,983)		(5,629,734)		(18,320,575)		(17,
WARRANT INDUCEMENT, INTEREST AND OTHER EXPENSI	Œ	(39,801)		(62,028)		(236,714)		(2,
LOSS BEFORE INCOME TAXES		(6,047,784)	_	(5,691,762)		(18,557,289)		(19,
INCOME TAXES		_		_		(739)		
NET LOSS AND COMPREHENSIVE LOSS	\$	(6,047,784)	\$	(5,691,762)	\$	(18,558,028)	\$	(19,
Deemed dividend related to warrants down round provision		(636,370)		_		(636,370)		
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$	(6,684,154)	\$	(5,691,762)	\$	(19,194,398)	\$	(19,
NET LOSS PER SHARE	_		_					
- Basic	\$	(2.42)	\$	(0.25)	\$	(8.26)	\$	
- Diluted	\$	(2.42)	\$	(0.25)	\$	(8.27)	\$	
WEIGHTED AVG NUMBER OF SHARES OUTSTANDING								
- Basic		2,767,440		23,018,235		2,322,749		17,
- Diluted		2,759,614		23,018,235		2,320,111		17,