
**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, 2018

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 November 13, 2018, we issued a press release announcing our financial results for the three and nine months ended September 30, 2018. 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, 2018.](#)

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.

BIOCEPT, INC.

Dated: November 13, 2018

By: /s/ Michael W. Nall

Name: Michael W. Nall

Title: Chief Executive Officer



Biocept Reports Third Quarter 2018 Financial Results

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

SAN DIEGO (November 13, 2018) – 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, 2018, and provides an update on its business progress.

“Progress continues on multiple fronts to support our future growth,” said Michael Nall, President and CEO of Biocept. “We have restructured our commercial organization with the recent hiring of a team of industry veterans who have a proven track record of success in the diagnostics market. Under the leadership of our new Chief Commercial Officer, Edwin Hendrick, we have developed new marketing strategies with a focused approach on specific market segments. We are also launching new programs to further engage our current customers as we continue to seek to broaden adoption of our Target Selector™ platforms.

“As an update on our collaboration with Thermo Fisher Scientific, we expect to complete validation of the molecular oncology assay panel before the end of 2018, and we anticipate being in position for commercial launch in 2019. At that time, Biocept will be the only liquid biopsy company offering both individual cancer biomarker tests along with the option of a larger oncology assay panel,” he added.

Review of Third Quarter and Recent Accomplishments

Collaborations

- Entered into an agreement with Highmark Heath, part of the Allegheny Health Network, to evaluate the clinical utility and cost effectiveness of Target Selector™ in patients diagnosed with non-small cell lung cancer (NSCLC). More than 10% of the 100 patients expected to participate have been enrolled in the program.
- Entered into a partnership with the Moores Cancer Center at UC San Diego Health to conduct two clinical studies in patients with a variety of solid tumors. These studies will use Target Selector™ to detect circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA), and compare results with findings from computed tomography (CT) or positron emission tomography (PET) scans. More than 10% of patients have been enrolled in these studies.
- Entered into a provider agreement with Alliance Global FZ, LLC to market and distribute Target Selector™ liquid biopsy tests in the United Arab Emirates and select countries in the Middle East, North and Sub-Saharan Africa and Southeast Asia. All diagnostic testing services will be performed in Biocept's CLIA-certified laboratory in San Diego with Alliance Global responsible for sales, marketing and distribution.

Clinical Data Presentations

- Presented two posters at the International Association for the Study of Lung Cancer's 19th World Conference on Lung Cancer featuring clinical data sets highlighting the ability of our Target Selector™ technology platforms to detect and monitor actionable biomarkers in patients

diagnosed with NSCLC. The first study was conducted with a large academic medical center and evaluated CTC count in blood in order to demonstrate response to treatment. The second poster, presented with a pharmaceutical partner, demonstrated the utility of CTCs and ctDNA in blood and cerebrospinal fluid (CSF).

Intellectual Property

- Obtained patent in Japan for Switch-Blocker technology that is core to Target Selector™ assays for analysis using real-time PCR, Sanger sequencing and next-generation sequencing.
- Awarded a Canadian patent covering the use of microchannels for the capture and detection of any target of interest, including proteins and nucleic acids, as well as the capture of cancer or other cells that can be used for molecular analysis in blood and other biological fluids.
- Granted patent in seven European countries for our Target Selector™ ctDNA assays featuring our Switch-Blocker technology.

Corporate

- Appointed Edwin C. Hendrick as Senior Vice President, Chief Commercial Officer. Mr. Hendrick brings more than 25 years of sales and commercial leadership experience in the healthcare industry including senior level commercial and operational positions in the clinical diagnostics field.
- Strengthened commercial team by naming Scott Nicholson as Vice President of Sales – US, and Cory Dunn as Vice President of Marketing. Mr. Nicholson has 24 years of experience in the medical laboratory industry with a focus in oncology for the physician and hospital markets, and Ms. Dunn has over 15 years of commercial marketing experience in the life sciences industry, specializing in diagnostic testing services for oncology.
- Entered into a securities purchase agreement with accredited institutional investors pursuant to which we sold approximately \$2.5 million in gross proceeds of common stock and warrants.
- Completed a shareholder rights offering raising gross proceeds of approximately \$11.6 million.

Third Quarter Financial Results

Revenues for the third quarter of 2018 were \$762,000, compared with \$1.1 million for the third quarter of 2017. During the first quarter of 2017, the Company converted from cash-based revenue recognition for its commercial revenues to accrual-based revenue recognition. Of the \$1.1 million of revenues recognized during the third quarter of 2017, \$0.9 million were related to revenues recognized on an accrual basis, while \$102,000 were related to revenues recognized upon the receipt of cash. This compares with the third quarter of 2018, when \$762,000 of revenues were recognized on an accrual basis and no revenues were recognized upon the receipt of cash. For the third quarter of 2018, revenues included \$698,000 in commercial test revenues, and \$63,000 in development services test revenues.

Biocept reported 964 total samples in the third quarter of 2018, compared with 1,343 total samples in the third quarter of 2017. Total samples include billable samples and samples from research activities, assay validations and other non-billable sources. The Company accessioned 878 billable samples in the third quarter of 2018, compared with 1,203 billable samples for the third quarter of 2017.

Cost of revenues for the third quarter of 2018 of \$2.5 million was unchanged from the prior year period. Cost of revenues in the 2018 period was impacted by an increase in expenses associated with validating the Thermo Fisher molecular oncology assay panel, and an increase in costs associated with calibrations and CLIA validations to improve upon existing equipment specifications and testing protocols. In

addition, we continue to maintain laboratory capacity to accommodate higher volumes as we work to improve our growth trends.

Research and development (R&D) expenses for the third quarter of 2018 were \$1.1 million, compared with \$857,000 for the third quarter of 2017, with the increase due primarily to the higher proportion of allocated laboratory costs associated with increased research and development activities and cost of research studies in collaboration with academic and healthcare institutions.

General and administrative (G&A) expenses for the third quarters of 2018 and 2017 were unchanged at \$1.8 million.

Sales and marketing expenses for the third quarter of 2018 were \$1.4 million, compared with \$1.7 million for the third quarter of 2017, a decrease of \$272,000, or 16%, primarily driven by a reduction in headcount-related expenses and sales commissions due to lower sales volume.

The net loss for the third quarter of 2018 was \$6.0 million, or \$2.42 per share on 2.8 million weighted-average shares outstanding. This compares with a net loss for the third quarter of 2017 of \$5.8 million, or \$5.90 per share on 987,000 weighted-average shares outstanding.

Nine Month Financial Results

Revenues for the first nine months of 2018 were \$2.4 million, compared with \$4.1 million for the first nine months of 2017, and included \$2.2 million in commercial test revenues, \$160,000 in development service test revenues and \$9,000 in revenues for CEE-Sure blood collection tubes. As a result of the change to accrual-based revenue recognition in 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.

Biocept reported 2,958 billable samples during the first nine months of 2018, compared with 3,535 billable samples for the first nine months of 2017. Total samples, which also include samples from research activities, assay validations and other non-billable sources, were 3,209 for the first nine months of 2018, compared with 3,994 total samples for the first nine months of 2017.

Cost of revenues for the first nine months of 2018 was \$7.6 million, compared with \$7.0 million for the first nine months of 2017, an increase of \$631,000 or 9%, driven primarily by an increase in the cost of materials due to assay validations, an increase in depreciation expense related to laboratory and computer equipment, software amortization, and allocated facility charges as we invested in upgrading our laboratory equipment and information system and facility maintenance.

R&D expenses for the first nine months of 2018 were \$3.2 million, compared with \$2.5 million for the prior-year period, an increase of \$724,000 or 29%, with the increase due primarily to higher lab allocation costs and headcount-related expenses as we focused on the development and deployment of next generation sequencing, support and implementation of data-intensive laboratory processes, and new product validations. In addition, R&D expenses also saw an increase related to cost of research studies in collaboration with academic and healthcare institutions.

G&A expenses for the first nine months of 2018 were \$5.4 million, compared with \$5.5 million for the first nine months of 2017, a decrease of \$98,000 or 2%, with the decrease driven primarily by a decrease in headcount-related expenses.

Sales and marketing expenses for the first nine months of 2018 were \$4.5 million, versus \$4.7 million for the first nine months of 2017, a decrease of \$227,000 or 5%, with the decrease driven primarily by a decrease in sales commissions due to lower sales volume, decrease in travel and related expenses, and other personnel related costs.

In the third quarter of 2018, we made a payment to Oxford Finance of approximately \$500,000, which included our final debt installment and other fees to extinguish our long-term debt facility.

The net loss for the first nine months of 2018 was \$18.6 million, or \$8.26 per share on 2.3 million weighted-average shares outstanding. This compares with a net loss for the first nine months of 2017 of \$15.9 million, or \$18.53 per share on 861,000 weighted-average shares outstanding.

Cash and cash equivalents as of September 30, 2018 were \$9.0 million, compared with \$2.1 million as of December 31, 2017. The Company raised approximately \$12.5 million in aggregate net proceeds from a shareholder rights offering and a financing with certain institutional investors, both of which closed in the third quarter of 2018.

Biocept implemented a cost-reduction program to reduce expenses by an estimated \$1.0 million to \$1.5 million annually, in addition to the more than \$2 million reduction in annual cash spend, resulting from the payoff of the Company's long-term debt obligation in July 2018.

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 <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 10125618.

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 grow our business and drive adoption of our products, the success of our collaboration with Thermo Fisher Scientific and our ability to validate and commercially launch products as a result thereof, the benefits of our cost-reduction program, and our ability to increase physician adoption of our liquid biopsy platform, 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, 2017	September 30, 2018
		(unaudited)
<u>ASSETS</u>		
Cash	\$ 2,146,611	\$ 8,956,200
Accounts receivable, net	1,193,426	1,476,454
Inventories, net	498,702	581,498
Prepaid expenses and other current assets	416,600	636,746
TOTAL CURRENT ASSETS	4,255,339	11,650,898
FIXED ASSETS, NET	3,123,567	2,900,994
TOTAL ASSETS	\$ 7,378,906	\$ 14,551,892
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES, NET	\$ 4,661,345	\$ 4,439,087
NON-CURRENT LIABILITIES, NET	1,421,527	1,174,397
TOTAL LIABILITIES	6,082,872	5,613,484
SHAREHOLDERS' EQUITY	1,296,034	8,938,408
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 7,378,906	\$ 14,551,892

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended September 30,		For the nine months ended September 30,	
	(Unaudited)		(Unaudited)	
	2017	2018	2017	2018
Net revenues	\$ 1,111,411	\$ 761,591	\$ 4,073,437	\$ 2,390,772
Costs and expenses:				
Cost of revenues	2,487,054	2,481,916	6,985,213	7,616,473
Research and development expenses	856,698	1,089,746	2,455,947	3,179,612
General and administrative expenses	1,834,771	1,793,720	5,539,432	5,441,354
Sales and marketing expenses	1,675,852	1,404,192	4,701,030	4,473,908
Total costs and expenses	6,854,375	6,769,574	19,681,622	20,711,347
Loss from operations	(5,742,964)	(6,007,983)	(15,608,185)	(18,320,575)
Other income/ (expense):				
Interest expense	(88,269)	(63,764)	(385,172)	(230,677)
Other income	12,804	23,963	51,216	(6,037)
Total other income/ (expense):	(75,465)	(39,801)	(333,956)	(236,714)
Loss before income taxes	(5,818,429)	(6,047,784)	(15,942,141)	(18,557,289)
Income tax expense	(2,877)	—	(5,023)	(739)
Net loss and comprehensive loss	\$ (5,821,306)	\$ (6,047,784)	\$ (15,947,164)	\$ (18,558,028)
Deemed dividend related to warrants down round provision	—	\$ (636,370)	—	\$ (636,370)
Net loss attributable to common shareholders	\$ (5,821,306)	\$ (6,684,154)	\$ (15,947,164)	\$ (19,194,398)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	986,865	2,767,440	860,539	2,322,749
Diluted	986,865	2,759,614	860,539	2,320,111
Net loss per common share:				
Basic	\$ (5.90)	\$ (2.42)	\$ (18.53)	\$ (8.26)
Diluted	\$ (5.90)	\$ (2.42)	\$ (18.53)	\$ (8.27)

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