
**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 14, 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 August 14, 2018, we issued a press release announcing our financial results for the three and six-months ended June 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 August 14, 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: August 14, 2018

By: /s/ Michael W. Nall

Name: Michael W. Nall

Title: Chief Executive Officer

Biocept Reports Second Quarter 2018 Financial Results

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

SAN DIEGO (August 14, 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 six months ended June 30, 2018, and provides an update on its business progress.

“We strengthened our financial position by completing a shareholder rights offering yesterday which added over \$10 million to the balance sheet and by retiring our long-term debt in July, which reduces annual cash expenditures by more than \$2 million,” said Michael Nall, President and CEO of Biocept. “We have also undergone refinements to our sales strategy and our commercial team is now focused on the benefits of Target Selector™ for lung cancer profiling and monitoring, where the need for our liquid biopsy tests is high. Our sales team are educating physicians by utilizing case reports that were published in peer-reviewed journals earlier this year, along with the clinical guidelines issued by four prominent industry associations supporting the use of liquid biopsy testing in patients with lung cancer.

“We are making progress with our transition from a reference laboratory only to expanding into a diagnostic kit manufacturer with a global brand,” he added. “During the quarter we shipped our first proprietary blood collection tubes to our global distributor VWR and expanded our intellectual property protection to 28 issued patents globally. These achievements support the planned international launch of our research-use only (RUO) liquid biopsy kits in early 2019.

“We expect to complete validation of our liquid biopsy Next Generation Sequencing gene panel under our Thermo Fisher Scientific collaboration in the third quarter, at which time we will be the only company to offer both individual and panel biomarker tests. This collaboration provides for joint marketing of molecular diagnostics and opens opportunities to expand our customer base to pharmaceutical companies,” Mr. Nall concluded.

Review of Second Quarter and Recent Accomplishments

Collaborations

- Entered into an agreement with a large managed care organization to evaluate the clinical utility and cost effectiveness of Target Selector™ in patients diagnosed with non-small cell lung cancer (NSCLC). Biocept’s liquid biopsy testing will be used to profile patients who have been diagnosed with NSCLC and/or whose disease has progressed on EGFR-targeted therapy. Key objectives are to evaluate improvements in the molecular profiling rate of advanced NSCLC patients and reduce the overall cost of patient care.
 - Entered into a partnership with 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 CT or PET scans.
 - Launched CEE-Sure® blood collection tubes (BCTs) for research-use only under an exclusive international distribution agreement with VWR, a leading global provider of product and service
-

solutions to laboratory and production customers. CEE-Sure® BCTs allow for the transport of liquid biopsy samples at room temperature from the clinic to central laboratories conducting molecular and cellular analyses, with the ability to preserve both CTCs and cfDNA collected from the patient in the same tube.

- 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 and Publications

- Published a case report in the peer-reviewed journal *Clinics in Oncology* demonstrating the clinical utility of Target Selector™ CTC testing in the management of a patient with metastatic breast cancer. Biocept's CTC-based assay detected estrogen receptor (ER) expression and HER2 gene amplification, which enabled the patient to qualify for anti-HER2 therapy that extended her survival and improved her quality of life. Several prior attempts to gain this molecular information from tissue using standard image-guided biopsy were unsuccessful.
- Published a case report in the peer-reviewed journal *Oncology & Hematology Review* demonstrating the clinical utility of Biocept's Target Selector™ *ALK* gene rearrangement test. The CTC-based assay detected the *ALK* gene translocation in a patient diagnosed with NSCLC who subsequently received sequential *ALK* inhibitor therapies and exhibited excellent clinical response to the treatment.
- Announced the publication of a letter to the editor in the peer-reviewed *Journal of Thoracic Oncology*, the official journal of the International Association for the study of lung cancer. The letter outlined the ability of Biocept's Target Selector™ test to identify a *ROS1* gene rearrangement in a patient with lung cancer, confirming the results of a prior tissue biopsy. Another liquid biopsy method cited in the report failed to find this important cancer biomarker.

Patents

- Awarded a Canadian patent covering the use of Biocept's 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 protection in seven European countries for Biocept's Target Selector™ assays for ctDNA analysis using real-time PCR, Sanger sequencing and next-generation sequencing.

Corporate

- Completed a shareholder rights offering raising gross proceeds of approximately \$11.6 million.

Second Quarter Financial Results

Revenues for the second quarter of 2018 were \$822,000, compared with \$1.3 million for the second 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 \$1.3 million of revenues recognized during the second quarter of 2017, \$1.1 million were related to revenues recognized on an accrual basis, while \$159,000 were related to revenues recognized upon the receipt of cash, compared to the second quarter of 2018, when \$822,000 of revenues were recognized on an accrual basis and no revenues were recognized upon the receipt of cash. For the second quarter of

2018, revenues included \$761,000 in commercial test revenues, \$52,000 in development services test revenues and \$9,000 in CEE-Sure blood collection tubes.

Biocept accessioned 1,029 total samples in the second quarter of 2018, compared with 1,405 total samples in the second quarter of 2017. Total accessions include billable samples and samples from research activities, assay validations and other non-billable sources. The Company accessioned 996 billable samples in the second quarter of 2018, compared with 1,225 billable samples for the second quarter of 2017.

Cost of revenues for the second quarter of 2018 was \$2.7 million, compared with \$2.4 million for the second quarter of 2017, and increase of \$331,000, or 14%, due primarily to higher software amortization and other information technology and laboratory equipment costs, as well as direct costs associated with the automation of our laboratory operations including laboratory process improvements.

Research and development (R&D) expenses for the second quarter of 2018 were \$1.0 million, compared with \$842,000 for the second quarter of 2017, an increase of \$177,000, or 21%, due primarily to the addition of personnel for the development of new biomarker assays and a higher proportion of allocated laboratory costs in support of increased R&D activities.

General and administrative (G&A) expenses for the second quarter of 2018 were \$1.7 million, compared with \$1.8 million for the second quarter of 2017, a decrease of \$89,000, or 5%, driven primarily by the decrease in headcount-related expenses.

Sales and marketing expenses for the second quarter of 2018 were \$1.4 million, compared with \$1.7 million for the second quarter of 2017, a decrease of \$314,000, or 18%, primarily driven by lower headcount related expenses and cost reduction efforts initiated in the second quarter of 2018.

The net loss for the second quarter of 2018 was \$6.2 million, or \$2.70 per share on 2.3 million weighted-average shares outstanding. This compares with a net loss for the second quarter of 2017 of \$5.7 million, or \$6.32 per share on 901,000 weighted-average shares outstanding.

Six Month Financial Results

Revenues for the first six months of 2018 were \$1.6 million, compared with \$3.0 million for the first six months of 2017, and included \$1.5 million in commercial test revenues, \$96,000 in development services test revenues and \$9,000 in CEE-Sure blood collection tubes. Of the \$3.0 million of revenues recognized during the first six months of 2017, \$1.9 million were related to revenues recognized on an accrual basis, while \$1.1 million were 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 this change, the Company recognized total nonrecurring revenue of \$1.0 million 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 2,080 billable samples during the first six months of 2018, compared with 2,332 billable samples accessioned during the first six months of 2017. Total accessions, which also include

samples from research activities, assay validations and other non-billable sources, were 2,199 for the first six months of 2018, compared with 2,651 total samples for the first six months of 2017.

Cost of revenues for the first six months of 2018 was \$5.1 million, compared with \$4.5 million for the first six months of 2017, an increase of \$637,000 or 14%, driven primarily by an increase in facility and office expenses with respect to computer equipment, software amortization, depreciation expense, and allocated information technology and facility charges as we invested in upgrading our laboratory equipment and information system and maintain our facility.

R&D expenses for the first six months of 2018 were \$2.1 million, compared with \$1.6 million for the prior-year period, an increase of \$500,000 or 31%, 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. The Company continues to believe that focused investments in R&D are critical to its future growth and competitive position in the marketplace.

G&A expenses for the first six months of 2018 were \$3.6 million, compared with \$3.7 million for the first six months of 2017, a decrease of \$57,000 or 2%, with the decrease driven primarily by the decrease in headcount-related expenses.

Sales and marketing expenses for the first six months of 2018 were \$3.1 million, versus \$3.0 million for the first six months of 2017, an increase of \$45,000 or 1%, with the increase driven primarily by the increase in infrastructure related costs.

The net loss for the first six months of 2018 was \$12.5 million, or \$5.97 per share on 2.1 million weighted-average shares outstanding. This compares with a net loss for the first six months of 2017 of \$10.1 million, or \$12.58 per share on 805,000 weighted-average shares outstanding.

Cash and cash equivalents as of June 30, 2018 were \$2.6 million, compared with \$2.1 million as of December 31, 2017. In January 2018, the Company completed the sale of common stock and warrants raising \$13.3 million in net proceeds. In August 2018, the Company completed a shareholder rights offering raising gross proceeds of approximately \$11.6 million.

Biocept is implementing a cost-reduction program, which is expected to save an estimated \$1.0 million to \$1.5 million annually, in addition to the more than \$2 million reduction in annual cash expenditures from retiring its long-term debt obligation in July of this year.

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 10122826.

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 expand our business as a diagnostic kit manufacturer, the ability of recent developments to support future growth, the success of our collaboration with Thermo Fisher Scientific, 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

	<u>December 31,</u> <u>2017</u>	<u>June 30,</u> <u>2018</u>
		(unaudited)
<u>ASSETS</u>		
Cash	\$ 2,146,611	\$ 2,569,111
Accounts receivable, net	1,193,426	1,437,665
Inventories, net	498,702	537,037
Prepaid expenses and other current assets	416,600	854,921
TOTAL CURRENT ASSETS	<u>4,255,339</u>	<u>5,398,734</u>
FIXED ASSETS, NET	<u>3,123,567</u>	<u>2,892,576</u>
TOTAL ASSETS	<u><u>\$ 7,378,906</u></u>	<u><u>\$ 8,291,310</u></u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES, NET	\$ 4,661,345	\$ 4,505,481
NON-CURRENT LIABILITIES, NET	<u>1,421,527</u>	<u>1,258,261</u>
TOTAL LIABILITIES	<u>6,082,872</u>	<u>5,763,742</u>
SHAREHOLDERS' EQUITY	<u>1,296,034</u>	<u>2,527,568</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u><u>\$ 7,378,906</u></u>	<u><u>\$ 8,291,310</u></u>

BIOCEPT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the three months ended June 30,		For the six months ended June 30,	
	2017	2018	2017	2018
Net revenues	\$ 1,278,961	\$ 822,238	\$ 2,962,026	\$ 1,629,181
Costs and expenses:				
Cost of revenues	2,368,705	2,699,671	4,498,159	5,134,557
Research and development expenses	841,991	1,019,285	1,599,249	2,089,866
General and administrative expenses	1,798,026	1,708,970	3,704,661	3,647,634
Sales and marketing expenses	1,746,867	1,433,174	3,025,178	3,069,716
Total costs and expenses	6,755,589	6,861,100	12,827,247	13,941,773
Loss from operations	(5,476,628)	(6,038,862)	(9,865,221)	(12,312,592)
Other income/ (expense):				
Interest expense	(214,377)	(84,239)	(296,903)	(166,913)
Other income	—	(30,000)	38,412	(30,000)
Total other income/ (expense):	(214,377)	(114,239)	(258,491)	(196,913)
Loss before income taxes	(5,691,005)	(6,153,101)	(10,123,712)	(12,509,505)
Income tax expense	(2,146)	—	(2,146)	(739)
Net loss and comprehensive loss	\$ (5,693,151)	\$ (6,153,101)	\$ (10,125,858)	\$ (12,510,244)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	901,001	2,280,115	804,714	2,096,717
Diluted	901,001	2,280,115	804,714	2,096,717
Net loss per common share:				
Basic	\$ (6.32)	\$ (2.70)	\$ (12.58)	\$ (5.97)
Diluted	\$ (6.32)	\$ (2.70)	\$ (12.58)	\$ (5.97)

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